Reference

APR 10 1939

THE NATIONAL ARCHIVES

FEDERAL REGISTER

OF THE UNITED STATES

VOLUME 4 NUMBER 68

Washington, Saturday, April 8, 1939

Rules, Regulations, Orders

TITLE 6—AGRICULTURAL CREDIT

FARM CREDIT ADMINISTRATION

FCA 128.—NONPRODUCERS' OWNERSHIP OF VOTING MEDIA IN COOPERATIVE ASSOCIATIONS

APRIL 7, 1939.

Sec. 71.10 of Title 6, Code of Federal Regulations, is amended to read as follows:

"SEC. 71.10 *Nonproducers' ownership of voting media in cooperative associations.* Loans may not be made to the cooperative associations, other than to mutual fire insurance companies, in which more than 10 percent of the voting media are held by nonproducers, and in no case unless the association gives affirmative assurance that it will submit to its membership, for adoption at its next regular or special meeting, measures (unless such already exist) designed to bring about a situation under which all voting rights will be vested in producers. Unless such measures, satisfactory to the bank, are adopted, no additional loans may be made to such associations.

"Loans may not be made to mutual fire insurance companies in which more than 25 percent of the voting media are held by nonproducers. (Sec. 13, 49 Stat. 317, 12 U. S. C. 1134j; Sec. 14, 49 Stat. 317, 12 U. S. C. 1134c.) [Loan Guide, Subject 110, April 7, 1939]"

[SEAL] S. D. SANDERS,
Cooperative Bank Commissioner.

[F. R. Doc. 39-1183; Filed, April 7, 1939; 11:57 a. m.]

TITLE 16—COMMERCIAL PRACTICES

FEDERAL TRADE COMMISSION

[Docket No. 3051]

IN THE MATTER OF LANTEEN LABORATORIES, INC., ET AL.

SEC. 3.6 (t) *Advertising falsely or misleadingly — Qualities or properties of product:* SEC. 3.6 (x) *Advertising falsely or misleadingly—Results.* Representing, in connection with offer, etc., in commerce, of so-called feminine hygiene preparations and appliances sold under names of "Lanteen Blue", "Lanteen Lilac", "Lanteen Russet", etc., or any other preparation or appliance of similar ingredients or characteristics, that any of said preparations or appliances, whether used alone or in connection with any other preparation or appliance, forms or constitutes a competent treatment, remedy or preventive of ill health of any nature, or is of any beneficial therapeutic value; or will prevent conception; or that the appliance "Lanteen Brown", described as a diaphragm, or any other of said appliances, will fit all anatomies or all normal anatomies; prohibited. (Sec. 5, 38 Stat. 719, as amended by Sec. 3, 52 Stat. 112; 15 U. S. C., Supp. IV, sec. 45b) [Cease and desist order, Lanteen Laboratories, Inc., et al., Docket 3051, April 1, 1939]

SEC. 3.6 (a) 26) *Advertising falsely or misleadingly — Business status, advantages or connections of advertiser—Reputation:* SEC. 3.6 (z) *Advertising falsely or misleadingly—Scientific tests.* Falsely representing, in connection with offer, etc., in commerce, of so-called feminine hygiene preparations and appliances sold under names of "Lanteen Blue", "Lanteen Lilac", "Lanteen Russet", etc., or any other preparation or appliance of similar ingredients or characteristics, that any of said preparations or

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FEDERAL REGISTER

Published by the Division of the Federal Register, The National Archives, pursuant to the authority contained in the Federal Register Act, approved July 26, 1935 (49 Stat. L. 500), under regulations prescribed by the Administrative Committee, with the approval of the President.

The Administrative Committee consists of the Archivist or Acting Archivist, an officer of the Department of Justice designated by the Attorney General, and the Public Printer or Acting Public Printer.

The daily issue of the FEDERAL REGISTER will be furnished by mail to subscribers, free of postage, for $1 per month or $10 per year; single copies 10 cents each; payable in advance. Remit by money order payable to Superintendent of Documents, Government Printing Office, Washington, D. C.

Correspondence concerning the publication of the FEDERAL REGISTER should be addressed to the Director, Division of the Federal Register, The National Archives, Washington, D. C.

appliances has been tested and approved by an independent non-profit organization, or any organization, devoted to scientific research on questions involving the methods of preventing conception and the prevention, treatment and cure of the diseases, maladies and conditions peculiar to women, or that respondents are noted on account of the manufacture and sale of high class pharmaceutical products, prohibited. (Sec. 5, 38 Stat. 719, as amended by Sec. 3, 52 Stat. 112; 15 U. S. C., Supp. IV, sec. 45b) [Cease and desist order, Lanteen Laboratories, Inc., et al., Docket 3051, April 1, 1939]

SEC. 3.6 (ja) *Advertising falsely or misleadingly—History of product:* SEC. 3.6 (l) *Advertising falsely or misleadingly — Indorsements and testimonials:* SEC. 3.18 *Claiming indorsements or testimonials falsely.* Falsely representing, in connection with offer, etc., in commerce, of so-called feminine hygiene preparations and appliances sold under names of "Lanteen Blue", "Lanteen Lilac", "Lanteen Russet", etc., or any other preparation or appliance of similar ingredients or characteristics, that any of said preparations or appliances is prepared, designed, approved or recommended by a member or members of the medical profession, prohibited. (Sec. 5, 38 Stat. 719, as amended by Sec. 3, 52 Stat. 112; 15 U. S. C., Supp. IV, sec. 45b) [Cease and desist order, Lanteen Laboratories, Inc., et al., Docket 3051, April 1, 1939]

SEC. 3.6 (y) *Advertising falsely or misleadingly—Safety.* Representing, in connection with offer, etc., in commerce, of so-called feminine hygiene preparations and appliances sold under names of "Lanteen Blue", "Lanteen Lilac", "Lanteen Russet", etc., or any other preparation or appliance of similar ingredients or characteristics, that any of said preparations or appliances may be used with safety and without deleterious effects by all women, prohibited. (Sec. 5, 38 Stat. 719, as amended by Sec. 3, 52 Stat. 112; 15 U. S. C., Supp. IV, sec. 45b) [Cease and desist order, Lanteen Laboratories, Inc., et al., Docket 3051, April 1, 1939]

SEC. 3.6 (y 1) *Advertising falsely or misleadingly—Scientific or other relevant facts.* Representing, in connection with offer, etc., in commerce, of so-called feminine hygiene preparations and appliances sold under names of "Lanteen Blue", "Lanteen Lilac", "Lanteen Russet", etc., or any other preparation or appliance of similar ingredients or characteristics, that the use of a diaphragm, or the so-called diaphragm method, is the only method that has the approval of, or is recognized by, medical specialists, marriage hygiene clinics and hospitals as superior to all other methods for the prevention of conception, or that such an appliance or said method provides complete security against the hazards of "foreign" germ life, prohibited. (Sec. 5, 38 Stat. 719, as amended by Sec. 3, 52 Stat. 112; 15 U. S. C., Supp. IV, sec. 45b) [Cease and desist order, Lanteen Laboratories, Inc., et al., Docket 3051, April 1, 1939]

SEC. 3.6 (l) *Advertising falsely or misleadingly—Indorsements and testimonials:* SEC 3.6 (t) *Advertising falsely or misleadingly—Qualities or properties of product:* SEC. 3.6 (x) *Advertising falsely or misleadingly—Results:* SEC. 3.6 (ff 10) *Advertising falsely or misleadingly—Unique nature or advantages:* SEC. 3.18 *Claiming indorsements or testimonials falsely.* Representing, in connection with offer, etc., in commerce, of so-called feminine hygiene preparations and appliances sold under names of "Lanteen Blue", "Lanteen Lilac", "Lanteen Russet", etc., or any other preparation or appliance of similar ingredients or characteristics, that any of said preparations or appliances destroys germ life, gives double protection, insures complete reliability, provides complete security against the hazards of "foreign" germ life, acts as a prophylactic, has the full approval of specialists in the medical profession, marriage hygiene clinics or hospitals, is recognized as superior to all other products of a similar type, or will bring health, happiness and freedom to the user thereof, prohibited. (Sec. 5, 38 Stat. 719, as amended by Sec. 3, 52 Stat. 112; 15 U. S. C., Supp. IV, Sec. 45b) [Cease and desist order, Lanteen Laboratories, Inc., et al., Docket 3051, April 1, 1939]

United States of America—Before Federal Trade Commission

At a regular session of the Federal Trade Commission, held at its office in the City of Washington, D. C., on the 1st day of April, A. D. 1939.

Commissioners: Robert E. Freer, Chairman; Garland S. Ferguson, Charles H. March, Ewin L. Davis, William A. Ayres.

IN THE MATTER OF LANTEEN LABORATORIES, INC., A CORPORATION, LANTEEN MEDICAL LABORATORIES, INC., A CORPORATION, ALSO TRADING UNDER THE NAME MEDICAL BUREAUS OF INFORMATION, AND RUFUS RIDDLESBARGER, INDIVIDUALLY AND IN HIS OFFICIAL CAPACITY AS AN OFFICER OF SAID RESPONDENTS

ORDER TO CEASE AND DESIST

This proceeding [1] having been heard by the Federal Trade Commission upon the complaint of the Commission, the answer of respondents, testimony and other evidence taken before John L. Hornor and Robert S. Hall, examiners of the Commission, theretofore duly designated by it, in support of the allegations of said complaint, and in opposition thereto, briefs filed herein and oral arguments by William L. Taggart, counsel for the Commission, and by George T. Buckingham, of the law firm of DeFrees, Buckingham, Jones and Hoffman, counsel for the respondents, and the Commission having made its findings as to the facts and its conclusion that said respondents have violated the provisions of the Federal Trade Commission Act;

It is ordered, That the respondents, Lanteen Laboratories, Inc., a corporation, Lanteen Medical Laboratories, Inc., a corporation, also trading under the name Medical Bureaus of Information, their officers, agents, representatives and employees, and Rufus Riddlesbarger, individually and as an officer of the Lanteen Laboratories, Inc., and Lanteen Medical Laboratories, Inc., his representatives, agents and employees, directly or through any corporate or other device, in connection with the offering for sale, sale and distribution of so-called feminine hygiene preparations and appliances, now known as and sold under the names "Lanteen Blue," "Lanteen Brown," "Lanteen Lilac," "Lanteen Yellow," "Lanteen Pink," "Lanteen Russet," "Lanteen Rose," "Lanteen Green," "Lanteen Gray," or any other preparation or appliance composed of similar ingredients or possessing similar characteristics, under whatever name or names sold, in interstate commerce or in the District of Columbia, do forthwith cease and desist, directly or by implication, from representing:

[1] 2 F. R. 1127.

(1) That any of said preparations or appliances, whether used alone or in connection with any other preparation or appliance, forms or constitutes a competent treatment, remedy or preventive of ill health of any nature, or is of any beneficial therapeutic value;

(2) That the use of any of said preparations or appliances, whether used alone or in connection with others of said preparations or appliances, will prevent conception;

(3) That the appliance now known as and sold under the name "Lanteen Brown," described as a diaphragm, or any other of said appliances, will fit all anatomies or all normal anatomies;

(4) That any of said preparations or appliances has been tested and approved by an independent non-profit organization, or any organization, devoted to scientific research on questions involving the methods of preventing conception and the prevention, treatment and cure of the diseases, maladies and conditions peculiar to women, or that respondents are noted on account of the manufacture and sale of high class pharmaceutical products, when such is not the fact;

(5) That any of said preparations or apliances is prepared, designed, approved or recommended by a member or members of the medical profession, when such is not the fact;

(6) That any of said preparations or appliances may be used with safety and without deleterious effects by all women;

(7) That the use of a diaphragm, or the so-called diaphragm method, is the only method that has the approval of medical specialists, marriage hygiene clinics and hospitals, or that the use of the diaphragm or the so-called diaphragm method is recognized by medical specialists, marriage hygiene clinics and hospitals as superior to all other methods for the prevention of conception, or that such an appliance or said method provides complete security against the hazards of "foreign" germ life;

(8) That any of said preparations or appliances (a) destroys germ life, (b) gives double protection, (c) insures complete reliability, (d) provides complete security against the hazards of "foreign" germ life, (e) acts as a prophylactic, (f) has the full approval of specialists in the medical profession, marriage hygiene clinics or hospitals, (g) is recognized as superior to all other products of a similar type, or (h) will bring health, happiness and freedom to the user thereof.

It is further ordered, That the respondents shall, within thirty (30) days after service upon them of this order, file with the Commission a report in writing, setting forth in detail the manner and form in which they have complied with this order.

By the Commission.

[SEAL] OTIS B. JOHNSON, *Secretary.*

[F. R. Doc. 39-1175; Filed, April 6, 1939; 4:18 p. m.]

[Docket No. 3517]

IN THE MATTER OF COLUMBIA REFINING COMPANY

SEC. 3.6 (a) (22) *Advertising falsely or misleadingly—Business status, advantages or connections of advertiser—Producer status of dealer—Manufacturer:* SEC. 3.66 (g) *Misbranding or mislabeling—Producer status of dealer:* SEC. 3.96 (b) (5) *Using misleading name—Vendor—Producer or laboratory status of dealer.* Representing, in connection with offer, etc., in commerce, of motor oils and lubricants, through use of word "Refining," or any word or term of similar import and meaning, in its corporate name, catalogues, advertising material, or in any other manner, or through any means or device, that it is a refiner or manufacturer of motor oils and lubricants (other than greases), until and unless it owns and operates, or directly and absolutely controls, a refinery or plant wherein such motor oils and lubricants are manufactured or refined by it, prohibited. (Sec. 5, 38 Stat. 719, as amended by Sec. 3, 52 Stat. 112; 15 U. S. C., Supp. IV, sec. 45b) [Modified cease and desist order, Columbia Refining Company, Docket 3517, March 27, 1939]

United States of America—Before Federal Trade Commission

At a regular session of the Federal Trade Commission, held at its office in the City of Washington, D. C., on the 27th day of March, A. D. 1939.

Commissioners: Robert E. Freer, Chairman; Garland S. Ferguson, Charles H. March, Ewin L. Davis, William A. Ayres.

MODIFIED ORDER TO CEASE AND DESIST

This proceeding having been heard by the Federal Trade Commission upon the complaint of the Commission and the answer of respondent in which answer respondent admits all the material allegations of fact set forth in the complaint and states that it waives all intervening procedure and further hearings as to said facts, and the Commission, on January 18, 1939, having made its findings as to the facts and conclusion that said respondent had violated the provisions of the Federal Trade Commission Act, and having issued its order [1] to cease, and the Commission having on this date modified its said findings as to the facts and now being desirous of modifying its order to cease and desist so as to conform with its said modified findings as to the facts and conclusion, and being advised in the premises;

It is ordered, That the order to cease and desist issued on January 18, 1939 be, and the same is hereby, modified to read as follows:

It is ordered, That the respondent, Columbia Refining Company, its officers, representatives, agents and employees, directly or through any corporate or other device in connection with the offering for sale, sale and distribution of its motor oils and lubricants in commerce, as commerce is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

Representing through the use of the word "Refining" or any word or term of similar import and meaning in its corporate name, catalogues, advertising material, or in any other manner or through any means or device, that it is a refiner or manufacturer of motor oils and lubricants (other than greases) until and unless it owns and operates or directly and absolutely controls a refinery or plant wherein such motor oils and lubricants are manufactured or refined by it.

It is further ordered, That the respondent shall, within sixty (60) days after service upon it of this order, file with the Commission a report in writing setting forth in detail the manner and form in which it has complied with this order.

By the Commission.

[SEAL] OTIS B. JOHNSON, *Secretary.*

[F. R. Doc. 39-1177; Filed, April 6, 1939; 4:20 p. m.]

[Docket No. 3650]

IN THE MATTER OF W. H. COMSTOCK COMPANY, LTD.

SEC. 3.6 (t) *Advertising falsely or misleadingly—Qualities or properties of product:* SEC. 3.6 (x) *Advertising falsely or misleadingly—Results.* Disseminating, etc., any advertisements, by means of United States mails or in commerce, etc., intended or likely to induce purchase of "Comstock's Dead Shot Worm Pellets" or "Comstock's N and B Liniment", or any other preparations with substantially similar ingredients or therapeutic properties, and which represent that such preparation for treatment of worm infection is a specific medicine for worm infection, eliminates stomach or pin worms from the human body, or is unfailing in its action in the treatment

[1] 4 F.R. 461 DI.

of worm infection; or that such liniment preparation has therapeutic value in the treatment of, or relieves the pains of, rheumatism, lumbago or neuralgia, is a remedy or cure for, or has therapeutic value in the treatment of, chest colds, or has therapeutic value in the treatment of muscular pains of the human body, other than as a counter-irritant for muscular pains due to minor conditions, such as excessive exercise or fatigue; prohibited. (Sec. 5, 38 Stat. 719, as amended by Sec. 3, 52 Stat. 112; 15 U. S. C., Supp. IV, sec. 45b) [Cease and desist order, W. H. Comstock Company, Ltd., Docket 3650, March 27, 1939]

United States of America—Before Federal Trade Commission

At a regular session of the Federal Trade Commission, held at its office in the City of Washington, D. C., on the 27th day of March, A. D. 1939.

Commissioners: Robert E. Freer, Chairman; Garland S. Ferguson, Charles H. March, Ewin L. Davis, William A. Ayres.

ORDER TO CEASE AND DESIST

This proceeding having been heard by the Federal Trade Commission upon the complaint of the Commission and the answer of respondent, in which answer respondent admits all the material allegations of fact set forth in said complaint, and states that it waives all intervening procedure and further hearing as to said facts, and the Commission having made its findings as to the facts and conclusion that said respondent has violated the provisions of the Federal Trade Commission Act;

It is ordered, That the respondent, W. H. Comstock Company, Ltd., a corporation, its officers, representatives, agents and employees, directly or through any corporate or other device, do forthwith cease and desist from:

Disseminating, or causing to be disseminated, any advertisement by means of the United States Mails or in commerce as commerce is defined in the Federal Trade Commission Act, by any means, for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase of a preparation for the treatment of worm infection, now designated by the name of "Comstock's Dead Shot Worm Pellets", or a liniment preparation, now designated as "Comstock's N and B Liniment", or any other preparations composed of substantially similar ingredients or possessing substantially similar therapeutic properties, whether sold under said names or under any other names; or disseminating, or causing to be disseminated, any advertisement, by any means, for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase in commerce, as commerce is defined in the Federal Trade Commission Act, of said preparations, which advertisements represent, directly or through implication:

(a) That such preparation for the treatment of worm infection is a specific medicine for worm infection, eliminates stomach or pin worms from the human body, or is unfailing in its action in the treatment of worm infection;

(b) That such liniment preparation has therapeutic value in the treatment of, or relieves the pains of, rheumatism, lumbago or neuralgia;

(c) That such liniment preparation is a remedy or cure for, or has therapeutic value in the treatment of chest colds;

(d) That such liniment preparation has therapeutic value in the treatment of muscular pains of the human body, other than as a counter-irritant for muscular pains due to minor conditions, such as excessive exercise or fatigue.

It is further ordered, That the respondent shall within sixty (60) days after service upon it of this order, file with the Commission a report in writing, setting forth in detail the manner and form in which it has complied with this order.

By the Commission.

[SEAL] OTIS B. JOHNSON, *Secretary.*

[F. R. Doc. 39–1176; Filed, April 6, 1939; 4:18 p. m.]

TITLE 25—INDIANS

OFFICE OF INDIAN AFFAIRS

AMENDMENT OF THE REGULATIONS GOVERNING THE LEASING OF OSAGE RESERVATION LANDS FOR OIL AND GAS MINING

MARCH 24, 1939.

Title 25, Chap. 1, Office of Indian Affairs, Department of the Interior, Part 180, leasing of Osage Reservation lands for oil and gas mining, is amended by adding Section 180.60A which reads:

SEC. 180.60A *Unit operating area.* That for the purpose of preventing waste and to permit production of oil and gas in such manner as to promote the greatest ultimate recovery of oil from a source of common supply (single field or pool), a cooperative development or unit operating area shall be established by the oil inspector and delineated on a map. All lands lying within such defined area shall be subject to such specific requirements and regulations with reference to development and production as the oil inspector shall prescribe from time to time. All residue gas having its origin in such defined area and returned to the oil lessee after extraction of gasoline and other liquid products (except that necessary for operating purposes as elsewhere provided in these regulations) must be injected into the sand or horizon from which it was originally withdrawn for the purpose of increasing the recovery of oil. Only with the consent of the oil inspector first had in writing shall less than the full volume of such residue gas available be so injected. The oil inspector shall consent to the injection of less than said full volume only after a study of the area and a determination of the amount of gas necessary to be injected to effect the maximum ultimate recovery of oil and gas as required by the Act of March 2, 1929 (45 Stat. 1478). The foregoing is the reissuance of regulations approved, effectuated and given publication as of March 26, 1938.

OSCAR L. CHAPMAN, *Assistant Secretary of the Interior.*

[F. R. Doc 39–1178; Filed, April 7, 1939; 10:00 a. m.]

Notices

DEPARTMENT OF AGRICULTURE.

Food and Drug Administration.

IN THE MATTER OF PUBLIC HEARING FOR PURPOSE OF RECEIVING EVIDENCE UPON BASIS OF WHICH REGULATIONS MAY BE PROMULGATED PROVIDING FOR LISTING OF COAL-TAR COLORS WHICH ARE HARMLESS AND SUITABLE FOR USE IN FOODS, DRUGS, AND COSMETICS, DRUGS AND COSMETICS, AND EXTERNALLY APPLIED DRUGS AND COSMETICS; FOR CERTIFICATION OF BATCHES OF SUCH COLORS; FOR PROCEDURES THEREUNDER; AND FOR PAYMENT OF FEES THEREFOR

REPORT OF PRESIDING OFFICER, SUGGESTED FINDINGS OF FACT, CONCLUSIONS, AND ORDER

General Statement

Pursuant to, and under the authority of, a notice in the above-entitled matter, issued, upon his own initiative, and filed by the Secretary of Agriculture, on January 5, 1939, with the Archivist of the United States and published in the FEDERAL REGISTER, Saturday, January 7, 1939 (FEDERAL REGISTER, V. 4, No. 4, pp. 79–84), wherein the undersigned was designated as Presiding Officer to conduct in the place of the Secretary, a public hearing herein, such hearing being in conformity with Section 701, subsection (e) of the Federal Food, Drug, and Cosmetic Act (Sec. 701, 52 Stat. 1055; 21 U. S. C. 371 (e), and under and by virtue of the authority, in said notice specifically recited, of Sections 406 (b), 504, 604, and 706 of said Act (Sec. 406 (b), 52 Stat.

1049; 21 U. S. C. 346 (b); Sec. 504, 52 Stat. 1052; 21 U. S. C. 354; Sec. 604, 52 Stat. 1055; 21 U. S. C. 364; Sec. 706, 52 Stat. 1058; 21 U. S. C. 376), the said hearing was convened by the undersigned Presiding Officer at the time and place specified in said notice, a copy of which had been theretofore delivered by registered mail in apt time to all interested persons. The first portion of said notice, being that portion thereof setting forth the authority therefor, the purpose thereof, fixing the time and place of said hearing, and designating the Presiding Officer, was thereupon read and physically incorporated in the record of the proceedings.

Following and accompanying the aforesaid portion of said notice, and therewith incorporated by reference, and so issued, filed and published were proposed regulations for listing of coal-tar colors, certification of batches thereof, and payment of fees for such services. The said notice in its entirety, as published as aforesaid, was offered and received in evidence, being designated "Government's Exhibit No. 1." Thereupon, the Presiding Officer announced that the said proposed regulations were subject to adoption, amendment, or rejection, in whole or in part, by the Secretary of Agriculture, as the evidence adduced at the hearing warranted.

At the conclusion and before the adjournment of said hearing, the Presiding Officer announced that each interested person who had filed an appearance at the hearing would be informed of the date of the filing of the transcript of the evidence and the proceeding with the Filing Clerk, Office of the Solicitor, Department of Agriculture, Washington, D. C., and that ten days would be allowed from the date of the receipt of such notice for filing with such Hearing Clerk by such interested person of written arguments, proposed findings of fact, or both, based solely upon the evidence adduced at the hearing.

Each of the said interested persons was so informed by a letter transmitted by registered mail to the address given at the time appearance was filed. The suggested findings of fact herein were made, the suggested conclusions in the form of Regulations and the suggested order herein were drafted, after the expiration of the aforesaid ten days and after consideration of the written arguments and proposed findings so filed.

It appears that no controversial issues of fact arise upon the evidence in the transcript. The hereinafter suggested findings of fact set forth fully not only the ultimate facts, but also, incidentally, in many instances, by reason of the highly technical character of the scientific evidence, interrelated facts in a causative chain that more clearly indicate to one to whom the knowledge of the scientist is not familiar knowledge the ultimate facts.

By reason of the nature of the subject matter and the necessarily technical character of the evidence, it appears that some evidentiary matter, as well as some that may be considered argumentative, has almost unavoidably been included in the findings of fact. References are made, after each finding, to the pages of the transcript of the record that are pertinent.

In the absence of controversial issues, in view of the unusual nature of the subject matter, the highly technical character of the evidence, and the unusually full findings of the facts that are the most important and material with specific references to the transcript it does not appear to be necessary or advisable to set forth, or review, at length, in all its phases and ramifications, the 617 pages of evidence, the greater portion of which came from experts in the fields of chemistry, pharmacology, physiology, dermatology, medicine and coal-tar dye and color manufacturing.

The testimony of such witnesses for the Department as qualified as experts in all those fields except the last named, and also those expert witnesses in administrative procedures in the listing and certification of coal-tar colors for use in foods, drugs and cosmetics, in support of the Proposed Regulations as modified, corrected and changed by suggestions made by them, as well as by other interested persons in the course of the hearing, was introduced by the Department of Agriculture. Since such changes in the Proposed Regulations were so numerous, affecting every color of the 132 set up in the Proposed Regulations, as well as many of the specifications therefor, the specific changes suggested will not be set forth here, since they are set out in the hereinafter suggested findings of fact, but will be merely indicated and referred to for a better understanding of such findings.

The Proposed Regulations submitted by the Secretary (Government's Exhibit No. 1) contained administrative procedures for assuring representative samples, assuring and maintaining the identity and the integrity of the samples, the batches and the entire proposed certification system, as well as procedures leading up to the listing and certification of coal-tar colors and the actual certification of such colors. Such Proposed Regulations provided for the classification of all such colors to be listed for certification in the future, as well as those to be presently listed, in three groups (35.02 (a), (b) and (c)), according as they were found to be harmless and suitable for use for the restricted purposes specified for each group.

The most important changes in the proposed regulations suggested by the expert witnesses for the Department were the changes in nomenclature, relating to the common names of coal-tar colors and the technical or descriptive names of such colors. The reasons for such changes were fully set forth. The changes as to the common names proposed and urged by such witnesses were: (1) that those common names of the colors assigned in the proposed regulations which were taken from the Index of 1924 of the Society of Dyests and Colourists of England be eliminated, as well as all references to said Index, and (2) that a new and more uniform system of common names be used, such names to indicate clearly the purpose for which the color may be certified. The changes as to the technical or descriptive names proposed and urged by such witnesses were: (1) that the dual system followed in assigning the technical or descriptive names in the proposed regulations be abandoned, and (2) that one uniform system, namely, that adopted by the American Chemical Society, be followed in assigning all technical or descriptive names for such colors.

While the most important changes proposed by other interested persons who had filed appearances at the hearing were changes that were chiefly structural, or mechanical, with regard to the listing of lakes of coal-tar colors, in that the specifications were to be combined and grouped, the choice of substrata upon which the pure dye may be extended was enlarged so as to permit the use in all cases of any substrata permitted in any case under the specifications as originally proposed. These changes, the reasons for which were stated at length, were: (1) that all such lakes be eliminated from Section 35.02 (b) and (c) of the proposed regulations as so published; (2) that such lakes of coal-tar colors be changed from the category of individually listed straight colors to a category somewhat similar to and suggested by the term "mixture"; (3) that such lakes be combined and segregated into two groups, according to the restricted use for which the colors in each group may be listed; (4) that each of such colors be listed under a master specification, those of one group to be listed for certification for use in drugs and cosmetics to be internally used, and those of the other group for drugs and cosmetics to be externally applied; and (5) enlarging the choice of substrata, so as to permit the use in all cases within one of the groups of any substrata permitted in any case under the specifications as originally proposed for any such color.

Such rearrangement and regrouping, it was urged, would not only decrease and simplify the work of the Food and Drug Administration in certifying such colors, but also would be more practicable for those seeking certification, insure more representative samples, as well as eliminate the individual listing

of each of such colors as straight colors, with specifications for each. Thus the coal-tar colors presently proposed to be listed, as well as those to be listed in the future, would be placed in five major divisions, or groups (Sec. 135 (a), (b), (c), (d), and (e)), instead of three groups as set up in the proposed regulations in Section 35.02 (changed to Sec. 135.02 in the suggested regulations).

The expert witnesses of the Department not only offered no objections to the proposed changes referred to in the preceding paragraph, but testified in support thereof. Other interested persons at the hearing not only offered no objections to the changes in nomenclature proposed by witnesses for the Department, but also testified in support thereof. No testimony or evidence was offered in opposition to either of the suggested changes by the Department or by any other interested person.

No controversial issues, therefore, arise upon the record in connection with the suggested major changes, since neither the witnesses for the Department nor other interested persons offered any objections thereto; nor do any controversial issues arise in connection with proposed changes in individual specifications by other interested persons, since no direct, positive testimony was offered in support thereof.

Differences of opinion were expressed by other interested persons with regard to the meeting, in good manufacturing processes, of certain of the specifications for coal-tar colors, but such expressions related only to a few of the specifications for a few of the colors. Such opinions did not purport to be based upon general knowledge of the processes followed by coal-tar-color manufacturers, nor did they purport to be based upon laboratory tests of experts in the manufacture of the particular color in question. Such opinions so expressed concerned, in the main, isolated specifications of a variety of different colors. No positive, direct testimony was offered that was adverse to the testimony of expert witnesses of the Department relating to such suggested changes of specifications. In the circumstances, such expressions of doubt, based wholly upon opinions, even though such opinions were the opinions of experts, could not, standing alone and unsupported, be considered as substantial evidence.

No direct, positive testimony was introduced by other interested persons to controvert, or tending to controvert, the testimony introduced by the Department to the effect that the application of any coal-tar color to the orbital area is liable to cause serious consequences, even resulting in impairment or loss of sight, and that no coal-tar color should be considered for listing for use in that area.

In certain instances, the expert witnesses for the Department, on cross-examination, supported unconditionally certain suggested changes in the specifications made by other interested persons. In other instances, such support was conditioned upon the result of the analysis of additional samples that may be submitted and upon tests made in the laboratory of the Food and Drug Administration, and investigations made by such Administration. In these instances, however, no direct, positive evidence was offered in support of such suggested changes.

It is considered advisable to refer in some detail to one suggested change made by other interested persons, especially since one written argument was filed in support thereof and one against by other interested persons, and since some evidence was elicted on cross-examination of one of the witnesses of the Department that was urged as supporting such change. Reference is made to certain of the specifications for the color listed in the Proposed Regulations as "Orange SS" (changed to FD&C No. 2 by the suggested change in nomenclature). Upon cross-examination, one of the witnesses for the Department testified that if the specifications for "O-Toluidine" and "Beta-Naphthol" could not be met in good manufacturing processes, and he assumed from his knowledge of the person asking the question that such specifications could not be met, there would be no objection from the standpoint of toxicity to lowering each of those specifications. As to the specification for "pure Dye", the same witness, however, conditioned his approval upon the absence of certain impurities. This witness was not asked, on cross-examination, concerning other changes in the specifications for this color in the event the above-mentioned specifications were so changed. It was testified by the expert chemist who had charge of the setting up of the proposed chemical specifications in the Proposed Regulations that, in the event the specifications for "O-Toluidine" and "Beta-Naphthol" were lowered, it would be necessary also to change the specifications for "pure dye" and also for "melting point". No testimony was offered by other interested persons who proposed such changes in the specifications for O-Toluidine and Beta Naphthol as to the change that would be thereby necessitated in the specifications as to melting point, and no positive, direct, testimony was offered in support of a change of the specification for pure dye.

One of the other interested persons filed an argument in support of the changes in the specifications for O-Toluidine and Beta-Naphthol, Pure Dye and Melting point, but such argument, in the absence of evidence, could not, of course, supply direct, positive, and substantial evidence upon which such changes could be based, nor warrant a finding that the specifications for O-Toluidine and Beta-Naphthol could be met in good manufacturing processes. In the absence of any direct, positive testimony or evidence as to the several matters mentioned, and in support of such proposed changes in the specifications, the only positive, direct, and substantial evidence offered and appearing in the transcript of the evidence and the proceedings in support of the specifications as originally set up for this color in the proposed regulations should, it appears, stand; otherwise, it would be necessary to strike the color from the number of those to be listed.

Upon the basis of substantial evidence received at the hearing and appearing in the transcript of evidence, to which specific references are hereafter made in each instance following the findings, the undersigned Presiding Officer makes and suggests the detailed findings of fact hereinafter set forth; and he further suggests that the Secretary of Agriculture issue an order setting forth therein and as part thereof such findings of fact, omitting therefrom references to the pages of the transcript of evidence, and that in and by said order the regulations hereinafter set forth be promulgated.

Suggested Findings of Fact[1]

1

Coal-tar colors—scope of term. That coal-tar colors are materials consisting of one or more substances which either are made from coal-tar, or are derived synthetically from intermediates of the same identity as coal-tar intermediates. They include all substances from these sources which are themselves colored and impart their color to the substance to which they are applied, and they also include those compounds which do not themselves possess the color imparted to the substance to which they are applied but which, when applied to such substance, impart color. For example, Orange I is prepared from coal-tar intermediates. It is itself orange in color and when applied to a substance produces an orange color. Alizarin is a substance which is made either from coal-tar or from the root of the madder plant. It imparts color and is a coal-tar color regardless of whether a particular batch is derived from coal-tar or from a natural source. Paraphenylenediamine is an example of a coal-tar color which is colorless, but when applied to another substance, a chemical reaction results and color is imparted. In the manufacture of coal-tar colors all impurities are never

[1] The references in the findings of fact hereinafter to sections and subsections of the proposed regulations (Published in the FEDERAL REGISTER, January 7, 1939, Vol. 4, No. 4), and to suggested additions thereto, should be changed as follows: for 35.01, 135.01; for General Specifications under 35.02 (a), (b), (c), 135.02; for 35.02 (a), 135.03; for 35.02 (b), 135.04; for 35.02 (c), 135.05; for 35.03, 135.06; for 35.04, 135.07; for 35.05, 135.08; for 35.06, 135.09, for 35.07, 135.10; for 35.08, 135.11; for 35.09, 135.12; for 35.10, 135.13; for 35.11, 135.14; for 35.12, 135.15.

completely eliminated. Coal-tar colors may also include diluents or substrata. (R., pp. 94–6; 98; 100–5; 108; 229–31; 375; 432; 495; 498; 510; 550; Government's Exhibit No. 1)

2

Definitions of terms used in regulations. That the following technical terms when used in connection with any coal-tar colors, hereinafter referred to, are found to mean:

(1) A straight color is a coal-tar color listed in Section 35.02 of Government's Exhibit No. 1 and includes such impurities and substrata as are contained in such color. (R., p. 106; Government's Exhibit No. 1)

(2) The term "mixture" when applied to a coal-tar color means a coal-tar color made by mixing two or more straight colors, or one or more straight colors and one or more diluents. (R., p. 29; Government's Exhibit No. 1)

(3) A diluent is any component of a coal-tar color except a straight color. (R., pp. 29, 30, 108; Government's Exhibit No. 1)

(4) The expression "pure dye" refers exclusively to the coal-tar dye contained in a coal-tar color. It does not include any intermediate, impurity, diluent, substratum, or any material other than the coal-tar dye contained in a coal-tar color. (R., p. 103; Government's Exhibit No. 1)

(5) Substratum is the substance on which a pure dye in a lake is extended. (R., p. 108; Government's Exhibit No. 1)

(6) The term "alumina" means a suspension in water of precipitated aluminum hydroxide. (R., p. 120; Government's Exhibit No. 1)

(7) The term "blanc fixe" means a suspension in water of precipitated barium sulfate. (R., p. 120; Government's Exhibit No. 1)

(8) "Gloss white" means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(9) The term "mixed oxides" means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color), calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide. (R., p. 107; Government's Exhibit No. 1)

(10) A batch is a quantity of coal-tar color prepared or mixed by the manufacturer or person requesting certification and held intact for the purpose of receiving certifications. (R., pp. 23, 71; Government's Exhibit No. 1)

(11) A batch number is an identification number assigned to a batch of coal-tar color by the person requesting certification. (R., pp. 22, 71; Government's Exhibit No. 1)

(12) A lot number is an identification number assigned to a batch of coal-tar color by the Food and Drug Administration upon certification of such batch. (R., pp. 30, 75, 78; Government's Exhibit No. 1)

(13) The expression "externally applied drugs and cosmetics" refers to those drugs and cosmetics which are applied to the external parts of the body and not to the lips or to any body surface covered by mucous membrane and does not include any drugs or cosmetics which are taken internally. (R., pp. 35, 79; Government's Exhibit No. 1)

3

No coal-tar color in the orbital area. That coal-tar colors are not harmless for use in preparations applied to the eye. The anatomical structure of the eye includes the area bounded by the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. The application of coal-tar colors to this area may cause serious injury and even loss of sight. A coal-tar color which is certified for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, should not be certified for use in a product to be applied to the eye. A coal-tar color used in a product to be applied to the eye should be considered to be from a batch that has not been certified, even though such color is from a batch that has been certified for other use. (R., pp. 32, 33, 78, 234–37, 413, 437, 438, 498, 599, 433; Government's Exhibit No. 1)

4

Section 201 of Federal Food, Drug, and Cosmetic Act applicable. That the definitions and interpretations of terms contained in Section 201 of the Federal Food, Drug, and Cosmetic Act should be made applicable also to such terms when used in regulations for the listing of coal-tar colors, certification of batches thereof, and payment of fees for such service. (R., p. 82; Government's Exhibit No. 1)

5

Derived from coal-tar or synthesized. That coal-tar is derived from coal, and that coal-tar colors are synthesized from coal-tar derivatives. If coal is subjected to heating in absence of air, at approximately 1200 degrees centigrated, it then forms four products. The heating process in question is called "destructive distillation". The four products are, the gases which are used for illumination and heating; solid matter which is coke; liquid matter which is ammoniacal liquor, and semi-solid matter which is coal-tar. After coal-tar has been purified by a fractional distillation, usually five fractions are collected. The first fraction is collected up to approximately 100 degrees centigrade, and is called the first light oil. Between approximately 100 degrees and 170 degrees centigrade, the fraction collected is called the second light oil. From approximately 170 degrees to 240 degrees centigrade, the middle oil or carbolic oil is collected. From approximately 240 degrees to 270 degrees centigrade, heavy oil or creosote oil is collected, and between approximately 270 degrees and 400 degrees centigrade, green anthracene oil is collected. At this stage, approximately half the tar remains in the form of pitch that can be used for road paving, roofing, insulation, or other purposes. When the different fractions are subjected to additional purification, a variety of products are obtained. These products fall into three principal groups: first, the hydrocarbon, such as benzene, xylene, naphthalene, and anthracene; second, phenolic bodies, among which are carbolic acid, cresols, and cresylic acid; third, nitrogenous matter, such as aniline and pyridine. All three of these classes of materials, which are coal-tar derivatives, may be used as intermediates in the manufacture of coal-tar colors. The coal-tar colors listed in Government's Exhibit No. 1 and with the Specifications as therein set forth, are all colors that are susceptible of being produced from coal-tar intermediates by chemical reactions. (R., pp. 98–101 and 103; Government's Exhibit No. 1)

6

Coal-tar colors — common names — technical names — specifications. That the colors listed in Government's Exhibit No. 1, and each of them, are designated, first, with a common name, second, with a scientific name or technical description, and third, specifications limiting the amount of impurities that cannot be avoided in good manufacturing practice. (R., pp. 104–6; Government's Exhibit No. 1)

7

Purpose of technical name. That when a technical or descriptive name of any of the coal-tar colors listed in Government's Exhibit No. 1, together with specifications of impurities present in such colors as are set forth in said exhibit, is furnished to a properly qualified chemist, the chemist can examine objectively any of the said coal-tar colors actually submitted to him and determine whether or not such colors are of the identity disclosed by such technical name or description and fall within the confines of such specifications of impurities. (R., p. 106; Government's Exhibit No. 1)

8

Colors grouped according to use. It is found that the colors listed in Govern-

ment's Exhibit No. 1, Section 35.02, are properly listed in three essential subdivisions, namely those colors entitled to certification for use in foods, drugs, and cosmetics, those colors entitled to certification for use in drugs and cosmetics, and those colors entitled to certification for use in externally applied drugs and cosmetics. It is further found that no coal-tar color should be listed for certification unless it is harmless and suitable for the use for which it is listed. (R., p. 242; Government's Exhibit No. 1)

9

New system for common names—grouping. That the common names assigned to the colors listed in Section 35.02 of Government's Exhibit No. 1 are not sufficiently descriptive for the purpose of listing coal-tar colors for certification. That it is necessary to establish a system of nomenclature that indicates in the name assigned to each color something of what the color is and what it is to be used for. Accordingly, it is found, for example, that the name Guinea Green B, the common name that designates the first color listed in the first group set up in Section 35.02 of Government's Exhibit No. 1, should be called FD&C Green No. 1. The second color listed, Light Green SF Yellowish, should be called FD&C Green No. 2. The fourth color listed, Naphthol Yellow S, should be known as FD&C Yellow No. 1. In the second group under the system of nomenclature here found essential, the colors listed for use in drugs and cosmetics, shall be designated D&C; the basic shade of each color shall be stated, for example, Green or Red, and consecutive numbers assigned to all such colors. In the third group, the colors are to be designated as Ext D&C, the name of the predominant shade of the color given, and a consecutive number assigned to each color of each predominant shade. It is found that it is essential to use said system of grouping and nomenclature in the listing and certification of coal-tar colors in order to avoid confusion. (R., pp. 163, 164, 338, 339; Government's Exhibit No. 1)

10

Straight colors—certification. That batches of straight colors listed in Government's Exhibit No. 1 should be certified in accordance with the provisions of the regulations to be promulgated for use in food, drugs, and cosmetics, when batches of such colors meet the specifications to be enumerated in said regulations. (R. pp. 96, 97, 240, 314; Government's Exhibit No. 1)

11

Colour index abandoned. That with reference to the Colour Index of 1924 published by the Society of Dyers and Colourists of England, the utilization of numbers assigned in this publication to certain colors, is confusing and misleading when these numbers are applied to colors listed in Section 35.02 of Government's Exhibit No. 1. These numbers should not, therefore, appear in the regulations, and neither should there appear any reference whatever to the said Colour Index of 1924. (R., pp. 162, 338, 359; Government's Exhibit No. 1)

12

Descriptive chemical name—system of American Chemical Society. It is found that a uniform system of nomenclature is not followed in assigning the technical descriptions or names, being the names set up as the first specification, in each case, for the colors listed in Section 35.02 of Government's Exhibit No. 1. In some instances the technical names set up are names listed in the Colour Index of 1924, published by the Society of Dyers and Colourists of England, which said names are not completely and accurately descriptive and do not clearly indicate the components and identities of the colors to which they are assigned. In many other instances the technical names are not listed in the said Index, and in those cases the technical names assigned are based upon the system adopted by the American Chemical Society, in which the components and the identities of the color are clearly indicated. It is found as a fact that a uniform system of nomenclature in assigning technical names should be used in and throughout Section 35.02 of Government's Exhibit No. 1; and that the system of nomenclature most frequently used in said Section, being that adopted by the American Chemical Society, should be followed in assigning a technical description, or name, to each of the coal-tar colors listed in Government's Exhibit No. 1, and also to any coal-tar color that may be subsequently added to that list. (R., pp. 162, 165, 338, 339, 343; Government's Exhibit No. 1)

13

Straight coal-tar colors. That a straight color should be free from all impurities (other than those hereinafter named in specifications, in amounts found to be harmless and suitable for use) to the extent that such impurities can be avoided in good manufacturing practice. (R., pp. 606, 609, 611; Government's Exhibit No. 1)

14

Restricted use. That the coal-tar colors listed in Section 35.02 of Government's Exhibit No. 1 are harmless and suitable for the restricted uses indicated in paragraphs (a), (b), and (c), thereof, if they meet the specifications set up in Government's Exhibit No. 1, Section 35.02, paragraphs (a), (b) and (c), respectively, provided such specifications are modified in the manner hereinafter set forth, as approved and recommended at the hearing. (R., pp. 106, 107, 245, 604, 605, 606, 610, 611; Government's Exhibit No. 1)

15

(Guinea Green B) *FD&C Green No. 1.* That the common name of the first color listed in Government's Exhibit No. 1, Section 35.02 (a), Guinea Green B, should be changed to FD&C Green No. 1. This should be followed by the heading Specifications, and the technical description of this color should be changed from "Sodium salt of p-sulf-benzylethylaminofuchson-benzyl-ethylimonium sulfonate" to "Monosodium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)-diphenyl-methyl-ene]-[1-(N-ethyl-N-p-sulfoniumbenzyl)-$\Delta^{2,5}$-cyclohexadienimine]". (R., pp. 162, 163, 338, 339, 343; Government's Exhibit No. 1)

16

That in Government's Exhibit No. 1, Section 35.02 (a), the first specification that appears after the technical name of the substance of the color Guinea Green B, as changed to FD&C Green No. 1, is "Volatile matter (at 135° C.), not more than 10.0 percent." The impurities which are included in this color, as volatile matter, consist largely of moisture, but the term also includes any other materials which evaporate when the color is heated to 135° C. The limitation of 10.0% can be met in good manufacturing practice. A more strict limitation of volatile matter might produce a color so dry as to be difficult to handle and to maintain in the condition in which it is manufactured. This specification, as applied to said color, is found to be harmless and suitable for use in foods, drugs, and cosmetics. (R., pp. 107, 109, 249; Government's Exhibit No. 1)

17

FD&C Green No. 1—water insoluble matter. That in Government's Exhibit No. 1, Section 35.02 (a), under the color Guinea Green B, changed to FD&C Green No. 1, the second specification which appears after the technical name of the substance is "Water insoluble matter, not more than 0.5 percent". This color is a water soluble color and, therefore, any material contained therein which is not soluble in water is an impurity. Manufacturers who follow good commercial practice can produce batches of this color which contain less than 0.5 percent of water insoluble matter. The water insoluble matter cannot, even when good manufacturing practice is followed, be completely eliminated from this color. This specification is reasonable and necessary to insure the purity of the color, and within the limitation designated, is found to be harmless and suitable for use in foods, drugs, and cosmetics. (R., pp. 109, 250; Government's Exhibit No. 1)

18

FD&C Green No. 1—ether extracts. The next specification in said exhibit under said color now FD&C Green No. 1 is "Ether extracts, not more than 0.4 percent". This specification can be met if good manufacturing practice is followed in the preparation of the color. A determination of the ether extract measures the amount of the impurities in the form of uncombined intermediates which are present in the color. All intermediates cannot be completely removed from this or any color, and the specification of 0.4 percent for this color is a reasonable specification which, when followed, will render the color harmless and suitable for use in foods, drugs, and cosmetics, in this respect. (R., pp. 109, 250, 251; Government's Exhibit No. 1)

19

FD&C Green No. 1—chlorides and sulfates. That in Government's Exhibit No. 1, Section 35.02 (a), the fourth specification that appears after the technical name of the substance of the color Guinea Green B, as changed to FD&C Green No. 1, is "Chlorides and sulfates of sodium, not more than 6.0 percent". Chlorides and sulfates are salts that are either added or formed during the process of manufacturing this color. The limit of 6.0 percent is one that can be met in good manufacturing practice. It is found that this specification for chlorides and sulfates of sodium, not more than 6.0 percent, is a satisfactory one that does not render the color harmful or unsuitable for use in foods, drugs, and cosmetics. (R., pp. 107, 110, 251; Government's Exhibit No. 1)

20

FD&C Green No. 1—mixed oxides. That in Government's Exhibit No. 1, Section 35.02 (a), the fifth specification that appears after the technical name of the substance of the color Guinea Green B, changed to FD&C Green No. 1, is "Mixed oxides, not more than 1.0 percent". The impurities "mixed oxides" should not be present in amounts greater than 1.0% if good commercial practice is followed in the manufacture of the color. This limitation is found to be a proper one and does not render the color harmful or unsuitable for use in foods, drugs, and cosmetics. (R., pp. 107, 110, 252; Government's Exhibit No. 1)

21

FD&C Green No. 1—lead (as Pb.). That in Government's Exhibit No. 1, Section 35.02 (a), the sixth specification that appears after the technical name of the substance of the color Guinea Green B, changed to FD&C Green No. 1, is "Lead (as Pb), not more than 0.001 percent". The specification "Lead (as Pb), not more than 0.001 percent" is one that can be met in good manufacturing practice. The basis for the small amount of lead, as stated in the specification for the above color, is the background of medical opinion concerning the toxicity of lead and the opinion held generally by scientists particularly qualified to be familiar with the toxicity of lead, all of which appears in and has been comprehensively dealt with in medical and scientific literature. A larger percentage of lead in a coal-tar color to be used in foods, drugs, and cosmetics, might be dangerous to the health of the user. In this connection, two types of harm come from the ingestion of lead. The first is acute poisoning; the second is chronic poisoning. However, the amount of lead likely to be found in any color is so small that the only real problem involved is that of possible chronic poisoning. Not all lead that is ingested is eliminated, even when the amounts ingested are very small as there is an accumulation of lead in the organs of the body, particularly in the bones, and this accumulated lead may cause a serious form of lead poisoning. To prevent chronic lead poisoning, an amount of lead greater than that mentioned in the specifications, namely, not more than 0.001 percent, should not be permitted in coal-tar colors used in coloring food. Our natural foodstuffs contain lead, and thus we cannot get away from the ingestion of this poison in small amounts. To avoid adding substantially more lead to the daily intake, the amount of lead in coal-tar colors for use in foods should be held to a minimum. Lead is deposited in all the tissues and organs of the human body to some extent, but particularly in the kidneys and liver. Finally, as lead accumulates in these organs, it reaches a stage of accumulation where physical manifestations become evident. The amount of accumulated lead necessary to produce these physical manifestations is not the same in the case of all individuals since there are different degrees of susceptibility to lead poisoning. Some of the symptoms of chronic lead poisoning are, in its earliest stages, a debility and lassitude. Subsequently, the individual may become easily fatigued and exhibit general weakness. He may become pale, and constitpation is often an early symptom. A physical manifestation, known as wristdrop, where the extensor muscles of the arm are weakened by the presence of lead, frequently accompanies severe manifestations of chronic lead poisoning. Tremors, convulsions, and a wide variety of other untoward effects follow. Of particular significance are the effects of lead on the blood stream or the blood-forming organs, in which case an increase of the reticulocyte count of the blood results, and stippled cells appear in the blood stream. These changes in the blood are accompanied by anemia. Some persons manifest symptoms of chronic lead poisoning much earlier than other persons who suffer identical exposure. This is because of the different tolerance of the individuals to lead. The effect of lead taken internally is the same with respect to foods, drugs, and cosmetics Lead contained in cosmetics can be absorbed through the skin to which the cosmetic is applied, and after such lead enters into the system, it is capable of producing the systemic effects previously stated. Lead in cosmetics passes through the skin because some of the so-called insoluble forms of lead are not completely insoluble, and when exposed to the secretions of the skin, become soluble and are thus absorbed. In instances where drugs or cosmetics containing lead are applied to broken skin tissue, the lead may very easily be absorbed into the body. Lead has no known function in living tissue. The limitation of Lead (as Pb), in the percentages stated in Government's Exhibit No. 1, can be met in good manufacturing practice in the manufacture of the colors therein listed and the percentage of lead stated, the colors are not rendered harmful or unsuitable for the uses specified. (R., pp. 107, 110, 252–54, 256–59, 200, 261, 370; Government's Exhibit No. 1)

22

FD&C Green No. 1—arsenic (as As_2O_3). That in Government's Exhibit No. 1, Section 35.02 (a), the seventh specification that appears after the technical name of the substance of the color Guinea Green B, changed to FD&C Green No. 1, is "Arsenic (as As_2O_3), not more than 0.00014 percent", There is no reason why the above specifications may not be met by manufacturers of this color. In the percentage named, this poisonous substance has been reduced to an infinitesimal and comparatively harmless proportion. Arsenic, like lead, consists of two types of toxicity. These are acute arsenic poisoning and chronic arsenic poisoning. Because of the extremely small amounts of arsenic produced in the manufacture of coal-tar colors, it is necessary only to prevent the existence of quantities of arsenic that might result in chronic arsenic poisoning. Chronic arsenic poisoning manifests itself in ways quite similar to those manifested in instances of chronic lead poisoning, and for this reason physicians are unable to detect early stages of chronic arsenic poisoning. Arsenic is capable of being accumulated in the system. It also has an accumulative effect. Arsenic may cause severe skin injury. It may effect the liver, the peripheral nervous system, the blood-forming organs, or the blood system.

Its effects on the skin are flushing, redness, and edema. Sometimes this edema also occurs after the ingestion of arsenic. The skin manifestations may progress until the epidermal layer is seriously affected. This is manifested primarily by thickening of the soles of the feet and the palms of the hands. The entire epidermal layer of the body may peal off. If this happens, death ensues. Arsenic, when applied to the skin, is capable of causing a carcinomatous condition of the skin. The nervous symptoms resemble those which accompany a disease known as polyneuritis. Its effect upon the blood-forming organs and upon the blood may result in anemia. Because of these toxic manifestations of arsenic, its presence in any coal-tar color that is to be used in coloring any food, drug, or cosmetic, must be placed at the lowest possible minimum. The presence of arsenic (as As_2O_3) in the coal-tar colors listed in Government's Exhibit No. 1, in the percentages stated, does not render the colors harmful or unsuitable for the uses indicated. (R. pp. 110, 261; Government's Exhibit No. 1)

23

FD&C Green No. 1—heavy metals. That in Government's Exhibit No. 1, Section 35.02 (a), the eighth specification that appears after the technical name of the substance of the color Guinea Green B, changed to FD&C Green No. 1, is "Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace". It is practicable for manufacturers to restrict impurities of this nature to a mere trace if good manufacturing practice is followed. Heavy metals are present in coal-tar color as impurities that get in during manufacturing processes. They should not be present in the finished product in any appreciable amount. The proposed specification is reasonable. The term "trace" means below any figure that could be quantitatively set for heavy metals. When heavy metals appear only in such quantities that they are below any figure that could be quantitatively set for them, they do not render the color harmful or unsuitable for use in foods, drugs, and cosmetics. (R., pp. 110, 300, 302; Government's Exhibit No. 1)

24

FD&C Green No. 1—pure dye. That in Government's Exhibit No. 1, Section 35.02 (a), the ninth and last specification that appears after the technical name of the substance of the color Guinea Green B, changed to FD&C Green No. 1, is "Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent". This specification with regard to pure dye (as determined by titration with titanium trichloride) is one that can be met if good commercial practices are employed by manufacturers. This specification of pure dye is one that will not render the color harmful or unsuitable for use. (R., pp. 110, 302; Government's Exhibit No. 1)

25

Findings applicable to same or similar specifications for other coal-tar colors in Section 35.02 (a), (b), and (c). That the preceding findings of fact with reference to the specifications which appear in Government's Exhibit No. 1 under the listed color Guinea Green B, as changed to FD&C Green No. 1, dealing with volatile matter, water insoluble matter, ether extracts, chlorides and sulfates of sodium, mixed oxides, lead (as Pb), arsenic, heavy metals, and pure dye, are equally applicable to each of these same specifications wherever they subsequently appear in any of the colors listed in Section 35.02 (a), (b), and (c), of Government's Exhibit No. 1, and the facts stated as a basis for the adoption of such specifications for FD&C Green No. 1, are hereby specifically found to be applicable to each and every one of the said colors listed in Section 35.02 (a), (b), and (c), of Government's Exhibit No. 1, in every instance wherever such specifications appear; and where such specifications do appear and it is found that the numerical limitations therein given such specifications are necessary to insure the purity, harmlessness and suitability for use of the colors listed for the restricted purposes for which they are to be used, that such specifications heretofore found to be necessary for the color FD&C Green No. 1, are equally necessary to the colors subsequently listed in said Exhibit wherever said specifications appear in Section 35.02 (a), (b), and (c), of Government's Exhibit No. 1, irrespective of the fact that such specifications provide in some instances a different numerical limit necessary for the particular color, and that said numerical limits are different from those stated in the specifications found to be harmless and suitable for use in the color FD&C Green No. 1. (R. pp. 249–52, 259, 260, 300; Government's Exhibit No. 1)

26

Lakes should be grouped and segregated—composite specifications. That all of the individual lakes that are listed in Government's Exhibit No. 1, Section 35.02 (b) and (c), should be consolidated so as to have master specifications that are a composite of all of the specifications that have been set up under each of the said lakes listed in said Exhibit, all of which said specifications should be available for use in the manufacture of any of the said lakes; that the systems of nomenclature, hereinbefore adopted in the foregoing findings of fact both with respect to common and technical names, should be applied to all lakes hereby or hereafter listed for certification for use in drugs and cosmetics, and externally applied drugs and cosmetics, in exactly the same manner as they are applied to other straight colors that are hereby or that may hereafter be listed for certification for use in foods, drugs, and cosmetics. (R., pp. 530–47, 604–6, 610; Government's Exhibit No. 1)

27

(Light Green SF Yellowish) *FD&C Green No. 2.* That the common name of Light Green SF Yellowish, listed in Government's Exhibit No. 1, Section 35.02 (a), should be changed to FD&C Green No. 2 and the technical description of this color appearing under the heading "Specifications", should be changed to "Disodium salt of 4- (-[4-(N-ethyl-p-sulfobenzylamino) - phenyl] - (4-sulfoniumphenyl)-methylene) - [1-(N-ethyl-N-p-sulfobenzyl -$\triangle^{2,5}$ - cyclohexadienimine]. The remaining specifications of this color, except the specification "subsidiary dyes (as Guinea Green B) not more than 5.0 percent, were all found to be necessary and proper specifications for the color FD&C Green No. 1, and are hereby found to be also necessary and proper specifications for the color FD&C Green No. 2. The Specification "subsidiary dyes (as Guinea Green B) not more than 5.0 percent" should be changed to "subsidiary dyes (as FD&C Green No. 1) not more than 5.0 percent". This specification constitutes a measure of certain related dyes formed during the manufacture of this color; that the amount of these related dyes can by good commercial practice be kept down to 5.0 percent; that the related dyes cannot be completely excluded and that they are harmless and suitable for use if held below 5.0 percent. The said color, with the specifications in said Exhibit, is found to be harmless and suitable for use in food, drugs, and cosmetics. (R., pp. 112, 113, 303; Government's Exhibit No. 1)

28

(Fast Green FCF) *FD&C Green No. 3.* That the common name of the color Fast Green FCF listed in Government's Exhibit No. 1, Section 35.02 (a), should be changed to FD&C Green No. 3 and the technical description of this color should be changed to "Disodium salt of 4 - ([4 - (N-ethyl-p-sulfonbenzylamino) - phenyl] - (4-hydroxy-2-sulfoniumphenyl)-methylene) - [1-(N-ethyl-N-p-sulfobenzyl-$\triangle^{2,5}$-cyclohexadienimine]". Its specifications are all found to be appropriate as they appear in said Exhibit; and said color as therein set up is found to be harmless and suitable for use in food, drugs, and cosmetics. (R., p. 318; Government's Exhibit No. 1).

29

(Naphthol Yellow S) *FD&C Yellow No. 1.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a), as Naphthol Yellow S should be changed to FD&C Yellow No. 1, and the technical description appearing under the heading "Specifications" should read: "Disodium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid". The specifications set up for said color in said Exhibit with the exception of

"Martius Yellow, not more than 0.03 percent" have heretofore all been found to be appropriate for use in other colors and the findings of fact made with respect to such specifications previously given, are hereby incorporated in this finding and made a part hereof. The specification "Martius Yellow, not more than 0.03 percent" deals with the unsulfonated substance which remains in the finished product FD&C Yellow No. 1; that it is an intermediate, the proposed limitation for which can be met in good commercial practice; and that it is a toxic substance. It is found that if not more than 0.03 percent of Martius Yellow is contained in this color it will be harmless and suitable for use in food, drugs, and cosmetics. (R., p. 318; Government's Exhibit No. 1)

30

(Naphthol Yellow S—Potassium Salt) *FD&C Yellow No. 2.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a) as Naphthol Yellow S—potassium salt should be changed to FD&C Yellow No. 2, and the technical description of this color appearing under the heading "Specifications" in said Exhibit, should appear as "Dipotassium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid". The remaining specifications of this color having been previously found to be appropriate for other colors, this color is found to be harmless and suitable for use in foods, drugs, and cosmetics. (R., p. 318; Government's Exhibit No. 1)

31

(Yellow AB) *FD&C Yellow No. 3.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a), as Yellow AB should be changed to FD&C Yellow No. 3, and the technical description of this color appearing under the heading "Specifications" in said Exhibit, should appear as "1-phenylazo-2-naphthylamine". In this color as listed in Government's Exhibit No. 1, Section 35.02 (a), there are found a number of specifications concerning which findings have not heretofore been made. The first of these specifications is "Sulfated ash, not more than 0.3 percent". Sulfated ash is a measure of inorganic impurities, a form of impurity which cannot be entirely eliminated in the manufacturing process. However, this impurity will not cause the color to be harmful or unsuitable for use in foods, drugs, and cosmetics. The next two specifications not previously referred to in the preceding findings of fact are "water soluble matter, not more than 0.3 percent" and "matter insoluble in carbon tetrachloride, not more than 0.5 percent". These specifications are upon measures of impurity since FD&C Yellow No. 3 is insoluble in water but is soluble in carbon tetrachloride, and those materials which are soluble in water are impurities and likewise those materials which are not soluble in carbon tetrachloride are impurities. The numerical figures given can be met in good commercial practice and are necessary to insure the purity of the color. The next specification which has not been referred to in the preceding findings of fact, deals with intermediates. In this instance, a limitation of 0.05 percent is a reasonable one. This specification deals with uncombined intermediates which are present in the color in small amounts as impurities; that if good commercial practice is followed, the limitation proposed can be met, but it is not possible completely to remove all intermediates. The next specification as set up for this color in Government's Exhibit No. 1 that has not been referred to in the preceding findings of fact, is "melting point, not less than 99° C". The melting point gives a partial identification of the color and also serves as a good indication of its purity. The necessity for the remaining specifications set up for this color in Government's Exhibit No. 1, has previously been referred to in preceding findings of fact, all of which are applicable here. The said color as set up in the specifications in said Exhibit is found to be harmless and suitable for use in foods, drugs, and cosmetics. (R., pp. 114, 306, 318; Government's Exhibit No. 1)

32

(Yellow OB) *FD&C Yellow No. 4.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a) as Yellow OB, should be changed to FD&C Yellow No. 4, and the technical description for this color appearing under "Specifications" in said Exhibit, should appear as "1-o-tolylazo-2-naphthylamine". All of the remaining specifications under this color have been referred to in previous findings of fact, in which said specifications all occurred under other colors and it is found that this color subjected to the corrections herein indicated, is harmless and suitable for use in foods, drugs, and cosmetics under the specifications set up as aforesaid in Government's Exhibit No. 1. (R., p. 318; Government's Exhibit No. 1)

33

(Tartrazine) *FD&C Yellow No. 5.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a) as Tartrazine should be listed under the common name FD&C No. 5, and the technical description under "Specifications" in said Exhibit, should be "trisodium salt of 3-carboxy-5-hydroxy - 1 -p-sulfophenyl-4-p-sulfophenylazo-pyrazole." The specifications set up under said color in said Exhibit for "phenylhydrazine-p-sulfonic acid, not more than 0.1 percent", discloses this substance is an intermediate used in the manufacture of this color, and that the specification is necessary to limit the amount of the impurity to a figure which will permit the color to be used in foods, drugs, and cosmetics. This specification and the remaining ones set up under said color in said Exhibit, all of which have been previously referred to in preceding findings of fact, are found to be of such a character that they will not render the color harmful or unsuitable for use in foods, drugs, and cosmetics. (R. pp. 115, 116, 307 and 318; Government's Exhibit No. 1)

34

(Sunset Yellow FCF) *FD&C Yellow No. 6.* That the common name listed in Government's Exhibit No. 1, Section 35.02 (a) of the color therein referred to as Sunset Yellow FCF, should be listed under the common name FD&C Yellow No. 6, and the technical description in said Exhibit for said color under "Specifications", should be "disodium salt of 1 -p-sulfophenylazo- 2 -naphthol- 6 -sulfonic acid". The remaining specifications set up in said color in said Exhibit, have all previously been referred to in the preceding findings of fact and are hereby found to be within proper limitation to entitle this color to be listed for certification for use in foods, drugs, and cosmetics. (R., p. 318; Government's Exhibit No. 1)

(Ponceau 3R) *FD&C Red No. 1.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a) as Ponceau 3R, should be listed under the common name FD&C Red No. 1, and the technical description under "Specifications" set up under said color in said Exhibit, should read "disodium salt of 1-pseudocumylazo-2-naphthol-3, 6-disulfonic acid." The specifications "pseudo-cumidine, not more than 0.2 percent," has not been referred to in the preceding findings of fact. Pseudocumidine is an intermediate used in manufacture of this color and it should not exceed the limit stated in the proposed specifications. It cannot be entirely eliminated but manufacturers who employ good practices, will have no difficulty in meeting this specification. The next specification not previously referred to in the preceding findings is "lower sulfonated dyes, not more than 5.0 percent". This specification deals with dyes which are related to FD&C Red No. 1". Manufacturers can meet the figure stated. The next specification not previously referred to in the preceding findings of fact, is "boiling range of crude pseudocumidine, or of pseudo-cumidine obtained by reduction of the dye, 220–245° C". This specification deals with raw materials which are used in the manufacture of this dye and which consist of a mixture of pseudo-cumidines. This specification can be met in good manufacturing practice and is necessary in order to insure the uniformity of different batches of this color which may be submitted for certification. The remaining specifications, all of which have previously been referred to in preceding

findings of fact for other colors, are all found to be necessary for this color in the figures as stated in said Exhibit and are not harmful or unsuitable for use. (R. pp. 37, 116, 308, 318; Government's Exhibit No. 1)

36

(Amaranth) *FD&C Red No. 2.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a) as Amaranth should be listed under the common name FD&C Red No. 2, and the technical description under "Specifications" as set up in said Exhibit under said color, should read "Trisodium salt of 1-(4-sulfo-1-naphthylaso)-2-naphthol-3,6-disulfonic acid". The remaining specifications have previously been approved for other colors in the preceding findings of fact and it is found that subject to the changes indicated, the color as listed in Government's Exhibit No. 1 together with its specifications is suitable for use in foods, drugs, and cosmetics. R., p. 318; Government's Exhibit No. 1)

37

(Erythrosine) *FD&C Red No. 3.* That the common name of the color listed in Government's Exhibit No. 1, 35.02 (a) as Erythrosine should be listed under the common name FD&C Red No. 3, and the technical description under the word "Specifications" as set up for said color in said Exhibit, should read "disodium salt of 9-o-carboxyphenyl-6-hydroxy-2,4,5,7-tetraiodo-3-isoxanthone". The specification in said Exhibit for said color "sodium carbonate, not more than 0.5 percent" and the specification "sodium iodide, not more than 0.4 percent" have not previously been referred to in the preceding findings of fact. These specifications deal with types of impurities found or added during the process of manufacturing the dye. These specifications are practicable in good manufacturing practice. Another specification not previously referred to in the preceding findings of fact with reference to any color "permitted range of organically combined iodine in pure dye, 52.5–54.5 percent." To avoid ambiguity, this specification should be changed to read "permitted range of organically combined iodine in pure dye, free from water of crystallization, 56.8 to 58.5 percent". The numerical range proposed contemplates a tolerance of 0.85 or 1.0 percent below and above the theoretical figure which would represent the chemical composition of the pure dye. This tolerance is a practical tolerance since it can be met in good manufacturing practice; that the proposed specification as incorporated in Government's Exhibit No. 1 is ambiguous since it does not indicate whether or not the water of crystallization is to be taken into account; that the results of the test contemplated by the specification should be calculated on the basis of pure dye, free from water of crystallization, and that the specification should be as hereinbefore stated. The remaining specifications having been approved in preceding findings of fact with respect to other colors listed in said Exhibit, are hereby found to be necessary for use under this color. The said color with its specifications as aforesaid is hereby found to be harmless and suitable for use in foods, drugs, and cosmetics. (R., pp. 117, 309, 194, 195, 557, 318; Government's Exhibit No. 1)

38

(Ponceau SX) *FD&C Red No. 4.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a) as Ponceau SX should be listed under the common name FD&C Red No. 4, and the technical description under the "Specifications" as set up in said Exhibit, should read "disodium salt of 2-(5-sulfo-2,4-xylylazo)-1-naphthol-4-sulfonic acid". All of the specifications for said color appearing in said Exhibit having been previously referred to in the preceding findings of fact as being appropriate for use under other colors, are found to be appropriate for use under this color and the said color with its specifications as set forth in said Exhibit, is found to be harmless and suitable for use in foods, drugs, and cosmetics. (R., p. 318; Government's Exhibit No. 1)

39

(Orange I) *FD&C Orange No. 1.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a) as Orange I, should be listed under the common name FD&C Orange No. 1, and the technical description appearing under "Specifications" as set up in said Exhibit under said color, should read "Monosodium salt of 4-p-sulfophenylazo-1-naphthol". In said Exhibit is found a specification not previously referred to in connection with any other color, namely, "alpha-naphthol, not more than 0.1 percent". Alpha-naphthol is an intermediate which is used in the manufacture of this color and if good manufacturing practice is employed, the amount of this impurity in the finished coal-tar color can be restricted to the limit above-mentioned. The specification "Orange II (151), not more than 5.0 percent" which likewise is referred to in this instance for the first time deals with a related dye containing beta-naphthol instead of alpha-naphthol. This impurity can be limited to not more than 5.0 percent if good commercial practice is followed in the manufacture of the coal-tar color. The parenthetical statement "(151)" which appears in this specification should be deleted as it was an identifying number for the color set up in the Colour Index of 1924 published by the Dyers and Colourists of England. The remaining specifications all of which have been referred to in connection with other colors in the preceding findings of fact, are all found to be appropriate for use in this color. With the exceptions stated, the color as listed in said Exhibit is found to be harmless and suitable for use in foods, drugs, and cosmetics. (R., pp. 118, 119, 311, 312, 318; Government's Exhibit No. 1)

40

(Orange SS) *FD&C Orange No. 2.* That the color listed under the common name Orange SS in Government's Exhibit No. 1, Section 35.02 (a), should be listed under the common name FD&C Orange No. 2, and the technical description appearing under "Specifications" as set up in said Exhibit, should read "1-o-Tolylazo-2-naphthol". A specification not previously referred to and approved for colors in this group in the preceding findings of fact, is "o-Toluidine, not more than 0.05 percent". o-Toluidine is an intermediate used in the manufacture of this color and since it is an impurity, the amount of it which the color contains should be limited. Another specification not previously referred to and approved in the preceding findings of fact is "beta-naphthol, not more than 0.05 percent". Beta-naphthol is an intermediate used in the manufacture of FD&C Orange No. 2, and since it is an impurity, the amount of beta-naphthol which the color contains should be limited. The specifications for o-Toluidine and beta-naphthol are reasonable and practicable in good manufacturing processes. The remaining specifications for this color have been previously found to be suitable for other colors listed in said Exhibit, and as set up in said Exhibit under this color, they are also found to be necessary, proper and practicable. The said color as set up in the specifications in Government's Exhibit No. 1 is found to be harmless and suitable for use in foods, drugs, and cosmetics. (R. pp. 214–220; 312–13; 389–391; 407–8; Government's Exhibit No. 1)

41

(Brilliant Blue FCF) *FD&C Blue No. 1.* That the common name listed in Government's Exhibit No. 1, Section 35.02 (a) as Brilliant Blue FCF, should be listed under the common name FD&C Blue No. 1, and the technical description appearing under "Specifications" as set up in said Exhibit should read "Disodium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl] - (2-sulfoniumphenyl)-methylene)-[1-(N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine]." The only specification appearing in said Exhibit under this color not previously found to be appropriate for use in colors that are to be used in foods, drugs, and cosmetics is "sodium acetate, not more than 3.0 percent." Sodium acetate is a salt formed or added during the manufacture of colors which should be limited to an amount which can be met in good manufacturing practices. The said color, with the specifications as set up in said Exhibit are found to be harmless and suitable for use in foods, drugs, and cosmetics. All of these specifications have been referred to in the preceding

findings of fact with reference to other colors listed in said Exhibit under Section 35.02 (a). (R., pp. 135, 318, 325; Government's Exhibit No. 1)

42

(Indigotine) *FD&C Blue No. 2.* That the common name of the color listed in Government's Exhibit No. 1, Section 35.02 (a) as Indigotine should be listed under the common name FD&C Blue No. 2. The technical description of this color as it appears under the word "Specifications" is "sodium salt of p-sulfo - benzylethylamino - o - acid." The technical description should read "Disodium salt of 5,5'-indigotindisulfonic acid". The remaining specifications for this color, all of which have been previously referred to in the preceding findings of fact in connection with other colors listed in Section 35.02 (a) of Government's Exhibit No. 1, are hereby found to be necessary and the said color with the specifications as aforesaid, is found to be harmless and suitable for use in foods, drugs, and cosmetics. (R., p. 318; Government's Exhibit No. 1)

43

Lakes combined and grouped according to use. That all the coal-tar colors listed in Section 35.02 (b) and (c) of Government's Exhibit No. 1, in which the word "Lake" appears in the common name, being the name preceding in each case the word "Specifications", and in which the said word "Lake" is qualified, with few exceptions, by one of the following words: "Aluminum", "Barium", "Calcium", "Zirconium", "Sodium", or "Madder", should be eliminated and stricken as individual straight colors from the said Section 35.02 (b) and (c) and the said colors should be combined and segregated into two groups, and each group should be covered by a master specification conditioned upon the purposes for which such colors are to be listed and certified for use; that for one of said groups there should be specifications for all those lakes which are harmless and suitable for use in drugs and cosmetics, and for the other group all those colors which are harmless and suitable for use in externally applied drugs and cosmetics. That the coal-tar colors, herein referred to, in which the word "Lake" appears in the common name as aforesaid, which should be so segregated, combined and grouped are those set up in Section 35.02 (b) and (c) of Government's Exhibit No. 1 under common names as follows:

Guinea Green B—Aluminum Lake, Guinea Green B—Barium Lake, Light Green SF Yellowish—Aluminum Lake, Light Green SF Yellowish — Barium Lake, Fast Green FCF—Aluminum Lake, Fast Green FCF—Barium Lake, Naphthol Yellow S—Aluminum Lake, Naphthol Yellow S — Barium Lake, Tartrazine — Aluminum Lake, Tartrazine — Barium Lake, Tartrazine — Zirconium Lake, Quinoline Yellow—Barium Lake, Sunset Yellow—Aluminum Lake, Sunset Yellow—Barium Lake, Brilliant Lake Red R—Calcium Lake, Ponceau 2R—Aluminum Lake, Ponceau 2R—Barium Lake, Ponceau 2R—Calcium Lake, Ponceau 3R—Aluminum Lake, Ponceau 3R—Barium Lake, Lithol Rubin B—Aluminum Lake, Lithol Rubin B—Calcium Lake, Lake Red C—Barium Lake, Amaranth — Aluminum Lake, Amaranth — Barium Lake, Amaranth—Calcium Lake, Lithol Red — Aluminum Lake, Lithol Red—Barium Lake, Lithol Red—Sodium Lake, Lake Red D—Barium Lake, Lake Red D—Calcium Lake, Rhodamine B—Aluminum Lake, Dichlorofluorescein — Aluminum Lake, Erythrosine Yellowish—Aluminum Lake, Tetrabromofluorescein—Aluminum Lake, Erythrosine — Aluminum Lake, Alizarin — Madder Lake, Orange I—Aluminum Lake, Orange I—Barium Lake, Orange II — Aluminum Lake, Orange II—Barium Lake, Alphazurine FG—Aluminum Lake, Alphazurine FG—Barium Lake, Indigo—Aluminum Lake, Indigotine — Barium Lake, Metanil Yellow—Aluminum Lake, Fast Light Yellow — Aluminum Lake, Fast Light Yellow — Barium Lake, Pigment Scarlet — Barium Lake, and Pigment Scarlet—Calcium Lake. (R., pp. 530–47; 604–6; 610; Government's Exhibit No. 1)

44

(Light Green CF Yellowish) *D&C Green No. 4.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Light Green CF Yellowish" should be changed to read D&C Green No. 4. The technical description of the said color appearing under "Specifications" in said exhibit should read "Calcium salt of 4([4-(N-ethyl-p-sulfobenzylamino) - phenyl] - (4-sulfoniumphenyl) - methylene) - 1-[(N-ethyl-N-p-sulfobenzyl) $\Delta^{2,5}$-cyclohexadienimine]." Under the designation "Specifications" in said exhibit that is found under the common name of this color is the specification "Oxides of iron and aluminum, not more than 1.0 percent." The impurities dealt with in these specifications are comparable to the impurities "Mixed Oxides" that were referred to in the preceding findings of fact, wherein were discussed the specifications of the color Guinea Green B changed to FD&C Green No. 1, but since this color is a calcium salt the oxides of iron and the oxides of aluminum are the impurities which should be restricted, this limitation can be met if good manufacturing practices are employed. The remaining specification of this color have been previously referred to in preceding findings of fact and with the exception of the changes above set forth this color as listed in Section 35.02 (b) of Government's Exhibit No. 1 is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 122, 315; Government's Exhibit No. 1)

45

(Alizarin Cyanine Green F) *D&C Green No. 5.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Alizarin Cyanine Green F" should be changed to read D&C Green No. 5 and the technical description found under the "Specifications" for said color in said exhibit should read "Disodium salt of 1,4-bis(o-sulfo-p-toluino)-anthraquinone." It is found that the specification of said color "1:4-Dichloro-anthraquinone, not more than 2 percent" is for an intermediate no longer used in the manufacture of the color and that the intermediate now used in the manufacture of the color "1:4-Di-hydroxy-anthraquinone" should be substituted in the original specification. This impurity, which should not be present in an excessive amount, is one that cannot be completely eliminated even through good commercial practice but the intermediate is entirely harmless for use in said color in the percentage named. The remaining specifications, all of which have been referred to in preceding findings of fact with respect to other colors, are appropriate for use with this color and the color with its said specifications as aforesaid and subject to the changes above enumerated is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 124, 315; Government's Exhibit No. 1)

46

(Quinizain Green SS) *D&C Green No. 6.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Quinizain Green SS" should be listed under the common name D&C Green No. 6 and the technical description under "Specifications" should read "1, 4-Bis(p-toluino)-anthraquinone." All of the specifications under this color as set up in the exhibit have been referred to in the preceding findings of fact with respect to other colors and this color, subject to the changes hereinbefore made, together with specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 124, 316; Government's Exhibit No. 1)

47

(Fluorescein) *D&C Yellow No. 7.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Fluorescein" should be listed under the common name "D&C Yellow No. 7" and the technical description under "Specifications" should read "3, 6-Fluorandiol." This color as listed in the said exhibit sets up two specifications that have not previously been referred to in connection with any other color. The first specification is "Insoluble matter (alkaline solution), not more than 1.0 percent." The second specification is "Ether extract (from alkaline solution), not more than 0.5%." The specifica-

tion with regard to insoluble matter is necessary to measure a form of impurity which may be found in this color because the color is not water soluble but is alkali soluble. Matter which is not soluble in alkali is an impurity. The specification with respect to ether extracts is a necessary one to measure other impurities. These tolerances can readily be met in good manufacturing practice. The remaining specifications for this color have been previously referred to in preceding findings of fact under other colors, and this color, with the changes indicated and with the specifications set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 126, 317; Government's Exhibit No. 1)

48

(Uranine) *D&C Yellow No. 8.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Uranine" should be listed under the common name of D&C Yellow No. 8 and the technical description under "Specifications" should appear as "Disoldium salt of 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." The specifications set up for this color in said exhibit are found to be appropriate with the exception that the specification for "Insoluble matter" should read "Water insoluble matter, not more than 1.0 percent" and that for "ether extracts" should read "Ether extracts, not more than 0.5 percent." This color is a water soluble color and both insoluble matter and ether extracts should be measured in water solutions instead of alkaline solutions if an accurate estimation of impurities is to be acquired. The parenthetical specification "(alkaline solution)" and "(from alkaline solution)" should be eliminated. The remaining specifications have been previously referred to in preceding findings of fact with respect to other colors. (R., pp. 126, 127, 317; Government's Exhibit No. 1)

49

(Uranine K) *D&C Yellow No. 9.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Uranine K" should be listed under the common name D&C Yellow No. 9 and the technical description under "Specifications" should read "Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." With the exception that the specifications read "Insoluble matter (alkaline solution), not more than 1.0 percent" and "Ether extracts (from alkaline solution), not more than 0.5 percent" should be changed to read "Water insoluble matter, not more than 1.0 percent" and "Ether extracts, not more than 0.5 percent," the specifications, as set up in said exhibit for said color are found to be appropriate and the said color, together with the said specifications, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 126, 127, 317; Government's Exhibit No. 1)

50

(Quinoline Yellow WS) *D&C Yellow No. 10.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Quinoline Yellow WS" should be listed under the common name D&C Yellow No. 10 and the technical description under "Specifications" should read "Disodium salt of disulphonic acid of 2-(2-quinolyl)-1, 3-indandione." This color contains a specification for "Quinaldine, not more than 0.2%" as set up in said exhibit that has not previously been referred to in any other preceding findings of fact. This specification relates to a substance that is an intermediate used in the manufacture of this color which substance is an impurity when present in D&C Yellow No. 10. The proposed limitation can be met if good manufacturing practice is followed. The remaining specifications for this color as set up in said exhibit are found to be appropriate and the said color, together with said specifications, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 128, 319; Government's Exhibit No. 1)

51

(Ponceau 2R) *D&C Red No. 5.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Ponceau 2R" should be listed under the common name "D&C Red No. 5" and the technical description under "Specifications" should be "Disodium salt of 1-zylylazo-2-naphthol-3, 6-disulfonic acid." The only specification not previously referred to in connection with some other color as set up for this color in said exhibit is "Xylidine, not more than 0.2 percent." Xylidine is an intermediate used in the manufacture of this color that when present in the finished color is an impurity. The above proposed specification can be met in good manufacturing practice. The remaining specifications set up for this color have previously been referred to in preceding findings of fact and it is found that this color, together with the said specifications, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 130, 320; Government's Exhibit No. 1)

52

(Lithol Rubin B) *D&C Red No. 6.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lithol Rubin B" should be listed under the common name D&C Red No. 6 and the technical description of this color appearing under "Specifications" should read "Monosodium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid." One of the specifications set up for this color in said exhibit "Ether extracts (isopropyl ether), not more than 0.5%" has not previously been referred to in the preceding findings of fact under any other color. This specification is designed to permit those impurities which are uncombined intermediates to be measured. The impurities cannot be completely eliminated and the proposed specification can be met if good manufacturing processes are employed. The remaining specifications have been referred to in preceding findings of fact under other colors and this color, together with the specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 131, 321; Government's Exhibit No. 1)

53

(Lithol Rubin BCA) *D&C Red No. 7.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lithol Rubin BCA" should be listed under the common name D&C Red No. 7 and the technical description for this color under "Specifications" should read "Calcium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid." The specifications for this color as set up in said exhibit are found to be necessary and the said color, together with the said specifications, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 106, 107, 245, 604, 605, 606, 610, 611; Government's Exhibit No. 1)

54

(Lake Red C) *D&C Red No. 8.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lake Red C" should be changed to have the common name D&C Red No. 8 and the technical name for this color appearing under "Specifications" in said exhibit should read "Sodium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2, naphthol." With the exception of "Lake Red C Amine, not more than 0.2 percent" all of the specifications set up for said color in said exhibit have been previously referred to in preceding findings of fact and the same are hereby found to be necessary for this color. The said specification "Lake Red C Amine, not more than 0.2 percent" deals with an intermediate which occurs even if good commercial practice is followed as an impurity in this color. It should not be present in the finished product in amounts greater than 0.2 percent. The said color, together with its said specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 132, 322; Government's Exhibit No. 1)

55

(Lake Red CBA) *D&C Red No. 9.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lake Red CBA" should be listed under the common name "D&C Red No. 9" and the technical description appearing under "Specifications"

should read "Barium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-naphthol." All of the specifications set up for this color in said exhibit with the exception of one have been previously referred to in preceding findings of fact with respect to other colors set up in said list. This one specification that has not been previously referred to is "Soluble barium in dilute HCl) (as $BaCl_2$), not more than 0.05 percent." This specification deals with soluble barium in dilute hydrochloric acid as barium chloride. Where barium salts are concerned the question of solubility is important as some of the barium may enter the digestive tract if it is contained in a coal-tar color for use in drugs and cosmetics and thus come in contact with the hydrochloric acid in the stomach. The hydrochloric acid in which the test for soluble barium is made should be approximately the same strength as is the hydrochloric acid in the stomach. The strength of hydrochloric acid in the stomach is approximately equal to pH2. The expression "(as $BaCl_2$)" indicates the form in which analytical results should be expressed. Barium is a natural occurring alkali earth metal that has some very peculiar stimulating and irritating effects upon the cells of the body and is a specific and peculiar cellular poison. The amounts of barium that would cause poisoning are extremely small. Its effects are peculiarly marked on the smooth muscle cells of the mammalian organism such as the smooth muscle cells of the gastro-intestinal tract and the smooth muscle cells in the walls of the blood vessels. Barium produces a particularly toxic effect on the muscle cells of the blood vessels of the heart. It is, therefore, generally recognized as a toxic substance. It is capable of causing gastro-intestinal disturbances if taken by mouth or if ingested in small amounts into the blood. While toxicologists and pharmacologists possess a great deal of information with respect to the toxicity of barium they do not have very much specific information as to the lowest amount that will cause toxicity. Barium, therefore, should be kept at the lowest possible level in all substances taken into or brought in contact with the body in order to avoid producing injuries. If barium is restricted to the amount set up in the specification for this color in said exhibit, no possible harm would result from the use of the color for the restricted purposes indicated in the exhibit. This is likewise true of other colors that contain barium set up in section 35.02 (c) which deals with drugs and cosmetics for external use. Barium in insoluble forms can be taken internally apparently without injury and the barium used in X-ray studies is an extremely insoluble form and is, in fact, barium sulphate. Occasionally barium sulphate, as used for the purpose of X-ray diagnosis has been known to contain small amounts of soluble barium. When this substance was ingested it produced serious injury. This finding with respect to soluble barium is expressly made applicable to all of the colors set up in said exhibit for listing under section 35.02. Chronic irritation is one of the certain elements that produces cancer and barium is an element that will irritate not only the skin where it is applied but when in the system it will, of course, irritate other cells. As a provisional matter pending further scientific research to determine whether barium may be completely eliminated from all coal-tar color to be certified for use in drugs and cosmetics, it is found that the tolerance above indicated for barium is one that will not produce any harmful effects when present in colors that are designed for use in coloring drugs and cosmetics. All of the remaining specifications as set up for the color have been previously referred to in preceding findings of fact relating to the specifications for other colors and this color, together with its specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 120, 268, 269, 270, 271, 273, 378, 288; Government's Exhibit No. 1)

56

(Lithol Red) *D&C Red No. 10.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lithol Red" should be listed under the common name D&C Red No. 10 and the technical description under "Specifications" as set forth under said color in said exhibit should appear as "Monosodiumsalt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalene-sulfonic acid." Among the specifications set up for said color in said exhibit is one that has not previously been discussed in any of the preceding findings of fact under any other color. This specification is "Tobias acid, not more than 0.2 percent." This specification is designed to limit the amount of this intermediate which is used in the manufacture of the color and small amounts of which remain in the color as an impurity. This impurity cannot be completely eliminated but the limit prescribed can be met in good manufacture practice. The remainder of the specifications set up for this color in said exhibit have in previous findings of fact been found to be appropriate for colors listed in said exhibit and the said color together with its specifications, as set up for said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 133, 323; Government's Exhibit No. 1)

57

(Lithol Red CA) *D&C Red No. 11.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lithol Red CA" should be listed under the common name D&C Red No. 11 and the technical description of this color which appears in Government's Exhibit No. 1 under the heading "Specifications" should appear as "Calcium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid." The specifications as set up for this color in Government's Exhibit No. 1 are found to be entirely appropriate and the color together with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

58

(Lithol Red BA) *D&C Red No. 12.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lithol Red BA" should be listed under the common name D&C Red No. 12 and the technical description of this color under the heading "Specifications" should appear as "Barium salt of 2-(hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid." The specifications set up for this color in said Exhibit have been previously referred to in preceding findings of fact under other colors and are found to be appropriate for use with this color. The said color together with the said specifications as set forth in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 133, 323; Government's Exhibit No. 1)

59

(Lithol Red SR) *D&C Red No. 13.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lithol Red SR" should be listed under the common name D&C Red No. 13 and the technical description of this color which appears in said exhibit under the heading "Specifications" should appear as "Strontium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid." The specifications, as set up for this color in said exhibit, have been previously referred to in preceding findings of fact with respect to other colors set up in said exhibit. These specifications are found to be appropriate for use in this color and the said color together with its specifications, as they appear in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 133, 323; Government's Exhibit No. 1)

60

(Lake Red D) *D&C Red No. 14.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as Lake Red D should be listed under the common name D&C Red No. 14 and the technical description of this color which appears in said exhibit under the heading "Specifications" should appear as "Monosodium salt of 1-o-carboxyphenylazo-2-naphthol." The specifications as set up for this color in said exhibit are found to be appropriate for use in this color. All these specifications have been previously referred to in preceding findings of fact under other colors set forth in said exhibit. This color together with its said specifications as set forth in said exhibit, is found to

be harmless and suitable for use in drugs and cosmetics. (R., pp. 134, 323; Government's Exhibit No. 1)

61

(Lake Red DBA) *D&C Red No. 15.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lake Red DBA" should be listed under the common name D&C Red No. 15 and the technical description of this color appearing under the heading "Specifications" should appear as "Barium salt of 1-o-carboxyphenylazo-2-naphthol." The specifications set up for this color in said exhibit are found to be appropriate as they have previously been referred to as being suitable for use in other colors in preceding findings of fact. The said color together with its said specifications as they appear in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 134, 323; Government's Exhibit No. 1)

62

(Lake Red DCA) *D&C Red No. 16.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Lake Red DCA" should be listed under the common name D&C Red No. 16 and the technical description of this color appearing under the heading "Specifications" therein, should appear as "Calcium salt of 1-o-carboxyphenylazo-2-naphthol." The specifications set up for this color in said exhibit are found to be appropriate as they have previously been referred to as being suitable for use in other colors in preceding findings of fact. The said color together with its said specifications as they appear in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 134, 323; Government's Exhibit No. 1)

63

(Toney Red) *D&C Red No. 17.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Toney Red" should be listed under the common name D&C Red No. 17 and the technical description of this color appearing under the heading "Specifications" therein, should appear as "1-p-Phenylazophenylazo-2-naphthol." This color has a specification for "Insoluble matter (in toluene), not more than 3.0 percent" that has not previously been referred to in connection with the specifications of any of the other colors in the preceding findings of fact. Since the color D&C Red No. 17 is soluble in toluene these materials contained in the color which are not soluble in toluene are impurities. This specification can be met if good manufacturing practice is employed. Another specification not previously referred to in connection with any other color in the preceding findings of fact is "Amino-azo-benzene, not more than 0.2 percent." This substance is an intermediate used in the manufacture of the color which cannot be completely removed. This impurity should be restricted to not more than 0.2 percent as is practicable in good manufacturing processes. The remaining specifications set up for this color in said exhibit have been previously referred to in preceding findings of fact, and they are found to be appropriate for this color also. The color together with its specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 134, 135, 324; Government's Exhibit No. 1)

64

(Oil Red OS) *D&C Red No. 18.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Oil Red OS" should be listed under the common name D&C Red No. 18 and the technical description of this color appearing under the heading "Specifications" therein, should appear as "1-Xylylazoxylylazo-2-naphthol." One specification for this color has not been discussed with respect to any other color in the preceding findings of fact. This specification is "Amino-azo-xylene, not more than 0.2 percent." This specification is an intermediate used in the manufacture of this color and when present in the finished color it represents an impurity which should not be permitted to be present in an amount in excess of 0.2 percent, which said tolerance can be met in good manufacture practice. The remaining specifications as set forth in said exhibit have been previously referred to and approved for other colors, and are found appropriate for this color. The said color together with its said specifications, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 135, 324; Government's Exhibit No. 1)

65

(Rhodamine B) *D&C Red No. 19.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Rhodamine B" should be listed under the common name D&C Red No. 19 and the technical description of this color appearing under the heading "Specifications" therein, should appear as "3-Ethochloride of 9-o-carboxyphenyl-6-diethylamino-3-ethylmino-3-isoxanthene." That the specification for "Ether extracts, not more than 0.5 percent," set up in said exhibit, should be changed to read "Ether extracts (from acid solution), not more than 0.5 percent." All of the specifications set up for this color in said exhibit have been previously referred to and approved for use with other colors, and are found to be appropriate with this color with the exception of the changes mentioned. The said color together with its specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 135, 324; Government's Exhibit No. 1)

66

(Rhodamine B-Acetate) *D&C Red No. 20.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Rhodamine B-Acetate" should be listed under the common name D&C Red No. 20, and the technical description of this color appearing under the heading "Specifications" therein should appear as "3-Ethoacetate of 9-o-carboxyphenyl-6-diethylamino-3-ethylimino-3-isoxanthene." The specification "Ether extracts, not more than 0.5 percent" as set up in the specifications for this color in said exhibit should read "Ether extracts (from acid solution), not more than 0.5 percent." The specification in said exhibit for this color "Sodium acetate, not more than 2.0 percent" is a necessary one in order to insure the purity of this coal tar color. Sodium acetate is a salt formed or added during the process of manufacture of the color that is an impurity that should be limited to not more than 2.0 percent. The remaining specifications have all been found to be appropriate for other colors listed in said exhibit and are found to be appropriate for this color. The said color, together with its specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 135, 325; Government's Exhibit No. 1)

67

(Dibromofluorescein) *D&C Orange No. 5.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Dibromofluorescein" should be listed under the common name D&C Orange No. 5. The technical description of this color appearing under the "Specifications" therein should appear as "4, 5-Dibromo-3, 6-fluorandiol." With respect to the specification for "Free bromide, not more than 0.02 percent," it is found that as traces of an impurity in the form of uncombined bromide are difficult to remove in the manufacture of this color, the amount present should be limited to not exceeding 0.02 percent. With regard to the specification "Permitted range of organically combined bromide in pure dye, 31.0–35.0 percent," this specification for all practical purposes is almost identical with the specification dealing with organically combined iodine previously referred to in the findings of fact in connection with the color listed in said exhibit as "Erythrosine." The proposed specification for "Dibromofluorescein" together with all the remaining specifications as set up in said exhibit, all of which have been previously approved for other colors, are hereby found to be appropriate for this color and the said color together with its said specifications as set up in said exhibit is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 137, 325, 326, 339; Government's Exhibit No. 1)

68

(Dibromofluorescein NA) *D&C Orange No. 6.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b) as "Dibromofluorescein NA" should be listed under the common name D&C Orange No. 6, and the technical description of this color appearing under the heading "Specifications" therein should appear as "Disodium salt of 4,5-dibromo-9-o-carboxyphenyl - 6 - hydroxy - 3 - isoxanthone." All of the specifications set up in the exhibit for this color have previously been approved for other colors and are found to be appropriate for use in this color. This color together with its specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 137, 326; Government's Exhibit No. 1)

69

(Dibromofluorescein K) *D&C Orange No. 7.* That the common name of the color "Dibromofluorescein K," recorded in Government's Exhibit No. 1, Section 35.02 (b), should be listed under the common name D&C Orange No. 7, and the technical description appearing under the heading "Specifications" therein should appear as "Dipotassium salt of 4,5-dibromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." Its specifications have been heretofore found to be appropriate as they appear in said exhibit. This color as set up in the specifications in said exhibit is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 137, 326; Government's Exhibit No. 1)

70

(Dichlorofluorescein) *D&C Orange No. 8.* That the common name of the color "Dichlorofluorescein," listed in Government's Exhibit No. 1, Section 35.02 (b), should be listed under the common name D&C Orange No. 8, and the technical description of this color appearing under the heading "Specifications" therein should appear as "4, 5-Dichloro-3,6-fluorandiol." The specification set up in said exhibit for said color of "Free chlorine, not more than 0.02 percent" has not been previously referred to in these findings with respect to any other color. Since this color is chlorinated the specification dealing with free chlorine is designed to limit the impurity which would remain as free chlorine. The proposed tolerance is comparable to a previously approved tolerance dealing with "free bromine." With respect to the specification set up for said color and said exhibit of "Permitted range of organically combined chlorine in pure dye, 16.0–19.0 percent," the requirement imposed by this specification would be for all practical purposes comparable to the requirement proposed for the color listed in said exhibit as "Erythrosine" which dealt with permitted range of organically combined iodine in pure dye. The remaining specifications are already found to be appropriate as they appear in said exhibit. This color as set up in said exhibit is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 137, 138, 318, 326, 339; Government's Exhibit No. 1)

71

(Dichlorofluorescein NA) *D&C Orange No. 9.* That the common name of the color "Dichlorofluorescein NA", as listed in Government's Exhibit No. 1, Section 35.02 (b), should be listed under the common name D&C Orange No. 9, and the technical description of this color appearing under the heading "Specifications" therein should appear as "Disodium salt of 9-o-carboxyphenyl-4,5 - dichloro-6-hydroxy-3- isoxanthone." The specifications for said color as they appear in said exhibit render said color harmless and suitable for use in drugs and cosmetics. (R., pp. 138, 316, 326; Government's Exhibit No. 1)

72

(Diiodofluorescein) *D&C Orange No. 10.* That the common name of the color "Diiodofluorescein" as listed in Government's Exhibit No. 1, Section 35.02 (b), should be changed to D&C Orange No. 10, and the technical description of this color appearing under the heading "Specifications" therein should appear as "4,5 - Diiodo-3,6-fluorandiol." That the specification set up in said exhibit for said color of "Free iodine, not more than 0.05 percent" is an appropriate specification which has not been referred to in connection with any previously mentioned color. The impurity free iodine cannot be completely eliminated in the manufacture of this color but the tolerance above referred to should be met in good manufacturing practice. The remaining specifications are already found to be appropriate as they appear in said exhibit. This color, with the specifications set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 138, 318, 327; Government's Exhibit No. 1)

73

(Erythrosine Yellowish NA) *D&C Orange No. 11.* That the common name of the color "Erythrosine Yellowish Na," as listed in Government's Exhibit No. 1, Section 35.02 (b), should be changed to D&C Orange No. 11, and the technical description of this color appearing under the heading "Specifications" therein should appear as "Disodium salt of 9-o-carboxyphenyl-6-hydroxy-4,5 - diiodo - 3 - isoxanthone." The said color, with its specifications, are found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 138, 318, 327; Government's Exhibit No. 1)

74

(Erythrosine Yellowish K) *D&C Orange No. 12.* That the common name of the color "Erythrosine Yellowish K," as listed in Government's Exhibit No. 1, Section 35.02 (b), should be listed under the common name D&C Orange No. 12, and the technical description of this color appearing under the heading "Specifications" therein, should appear as "Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-4,5 - diiodo - 3 - isoxanthone." This color, with its specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 138, 318, 327; Government's Exhibit No. 1)

75

(Erythrosine Yellowish NH) *D&C Orange No. 13.* That the common name of the color "Erythrosine Yellowish NH," as listed in Government's Exhibit No. 1, Section 35.02 (b), should be listed under the common name D&C Orange No. 13, and the technical description of this color under "Specifications" therein should appear as "Diammonium salt of 9-o-carboxyphenyl-6-hydroxy-4,5-diiodo-3-isoxanthone." This color, with its specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 138, 318, 327; Government's Exhibit No. 1)

76

(Tetrabromofluorescein) *D&C Red No. 21.* That the common name of the color "Tetrabromofluorescein", as listed in Government's Exhibit No. 1, Sec. 35.02 (b), should be listed under the common name "D&C Red No. 21". The technical description appearing under "Specifications" therein should read "2,4,5,7-Tetrabromo-3,6-fluorandiol". The specification "Volatile matter (at 135° C.), not more than 4.0 percent" appears as the specification for this color in said exhibit. The tolerance for volatile matter should be raised from 4.0 percent to 6.0 percent. The specification dealing with pure dye should be changed, consistent with the change for the volatile matter, so as to read "Pure dye (as determined gravimetrically), not less than 93.0 percent". The color, with the specifications of said exhibit as so changed, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 139, 172, 318, 327, 393, 412; Government's Exhibit No. 1)

77

(Eosin YS) *D&C Red No. 22.* That the common name of the color "Eosin YS", as listed in Government's Exhibit No. 1, Sec. 35.02 (b), should be listed under the common name "D&C Red No. 22", and the technical description under "Specifications" therein should read "Disodium salt of 2,4,5,7-tetrabromo-9-o-carboxyphenyl - 6 - hydroxy-3-isoxanthone". This color, with its specifications as contained in said exhibit is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 139, 318, 327; Government's Exhibit No. 1)

78

(Eosin YSK) *D&C Red No. 23.* That the common name of the color "Eosin YSK", as listed in Government's Exhibit No. 1, Sec. 35.02 (b), should be listed as "D&C Red No. 23". The technical description under "Specifications" therein should be "Dipotassium salt of 2,4,5,-7 - tetrobromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone". This color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 139, 318, 327; Government's Exhibit No. 1)

79

(Tetrachlorofluorescein) *D&C Red No. 24.* That the common name of the color "Tetrachlorofluorescein", as listed in Government's Exhibit No. 1, Sec. 32.02 (b), should be listed under the common name "D&C Red No. 24", and the technical description should be "2,4,5,7-Tetrachloro-3,6-fluorandiol". The color, with its specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 150, 318, 328)

80

(Tetrachlorofluorescein NA) *D&C Red No. 25.* That the common name of the color "Tetrachlorofluorescein NA", as listed in Government's Exhibit No. 1, Sec. 35.02 (b), should be listed under the common name "D&C Red No. 25", and the technical description should appear as "Disodium salt of 9-c-carboxyphenyl - 2,4,5,7-tetrachloro-6-hydroxy-3-isoxanthone". The color, with the other specifications, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 150, 318, 328; Government's Exhibit No. 1)

81

(Tetrachlorofluorescein K) *D&C Red No. 26.* That the common name of the color "Tetrachlorofluorescein K", as listed in Government's Exhibit No. 1, Sec. 35.02 (b), should be listed under the common name "D&C Red No. 26", and the technical description should appear as "Dipotassium salt of 9-o-carboxyphenyl-2,4,5,7-tetrachloro-6-hydroxy- 3 -isoxan - thone." This color, with the other specifications, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 150, 318, 328; Government's Exhibit No. 1)

82

(Tetrachlorotetrabromofluorescein) *D&C Red No. 27.* That the common name of the color "Tetrachlorotetrabromofluorescein" as listed in Government's Exhibit No. 1, Sec. 35.02 (b) should be listed under the common name "D&C Red No. 27", and the technical description of this color appearing under the heading "Specifications" therein should appear as "2,4,5,7-Tetrabromo-12, 13,14,15 - tetrachloro - 3,6 - fluorandiol". The specification in said exhibit for this color of "Free halogens, not more than 0.02 percent", has not previously been referred to in any findings with respect to any other color. This specification is designed to limit the presence of impurities of a type spoken of in commerce as halogens. These impurities cannot be completely eliminated but the tolerance set up can be met in good manufacturing practice. In said exhibit the specification "Permitted range of organically combined bromine in pure dye, 3815–42.5 percent", appears. This specification should read "Permitted range of organically combined bromine in pure dye, 38.5–42.5 percent". All the remaining specifications are found to be appropriate as they appear in said exhibit; and the said color, with the specifications as changed, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 151, 318, 328; Government's Exhibit No. 1)

83

(Phloxine B) *D&C Red No. 28.* That the common name of the color "Phloxine B", as listed in Government's Exhibit No. 1, Sec. 35.02 (b), should be changed to "D&C Red No. 28", and the technical description of this color under "Specifications" therein should read "Disodium salt of 2, 4, 5, 7-tetrabromo-9-(3, 4, 5, 6-tetrachloro - o- carboxyphenyl) - 6 - hydroxy-3-isoxanthone." This color, with the other specifications set up in said exhibit is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 151, 318 and 329; Government's Exhibit No. 1)

84

(Orange TR) *D&C Orange No. 14.* That the common name of the color "Orange TR" as listed in Government's Exhibit No. 1, Section 35.02 (b), should appear as "D&C Orange No. 14", and the technical description of this color under "Specifications" therein, should read "4, 5, 15-Tribromo-2, 7-dicarboxy-3, 6-fluorandiol". One specification for this color has not been previously referred to under any other finding with respect to any other color, namely, "Soluble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0%". This specification deals with the purity of the dye. Soluble matter is a substance that cannot be completely eliminated. If good manufacturing practice is followed, the specifications can be met. The color, with the other specifications in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 151, 318, 329; Government's Exhibit No. 1)

85

(Bluish Orange TR) *D&C Red No. 29.* That the common name of a color as listed in Government's Exhibit No. 1, Section 35.02 (b), as "Bluish Orange TR," should be listed as "D&C Red No. 29," and the technical description appearing under "Specifications" therein should be "1,4,5,8,15-Pentabromo-2,7-dicarboxy-3,6-fluorandiol". The color, with the other specifications in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 152, 318, 329; Government's Exhibit No. 1)

86

(Alizarin) *D&C Orange No. 15.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Alizarin", should be listed under the common name "D&C Orange No. 15", and the technical description appearing under "Specifications" therein should be "1,2-Anthraquinonediol". The specification in said exhibit reading "Ether extracts, not more than 1.0 percent" should be changed to read "Ether insoluble matter, not more than 1.0%". This color, with all the remaining specifications as set up in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 152, 318, 330; Government's Exhibit No. 1)

87

(Helindone Pink CN) *D&C Red No. 30.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Helindone Pink CN" should be listed under the common name "D&C Red No. 30", and the technical description appearing under "Specifications" therein, should be "5,5'-Dichloro - 3,3' - dimethylthioindigo." The specification "Matter, insoluble in xylene, not more than 1.0 percent" is one that has not previously been referred to in any of the findings with respect to any other color. This color is soluble in xylene and such materials as it may contain as are insoluble in xylene are impurities which should be limited. The specification "pure dye (as calculated from organically combined chlorine or sulfur), not less than 90.0 percent", should be changed to "Pure dye (as determined by titration with titanium trichloride), not less than 90.0%". The color, with the specifications as changed and with the other specifications in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 153, 318, 330; Government's Exhibit No. 1)

88

(Orange G) *D&C Orange No. 3.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Orange G", should be listed under the common name "D&C Orange No. 3", and the technical description appearing under "Specifications" should be "Disodium salt of 1-phenylazo - 2-naphthol - 6,8 - disulfonic acid". This color, with the other specifications in said exhibit, is found to be appropriate and harmless and suitable for use in drugs and cosmetics. (R., pp. 153, 154, 318, 331; Government's Exhibit No. 1)

89

(Orange II) *D&C Orange No. 4.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02

(b), as Orange II, should be listed under the common name "D&C Orange No. 4", and the technical description under "Specifications" therein, should be "Monosodium salt of 1-p-sulfophenylazo-2-naphthol". The color, with the other specifications in said exhibit, is found to be appropriate and to be harmless and suitable for use in drugs and cosmetics. (R., pp. 154, 318, 331; Government's Exhibit No. 1)

90

(Resorcin Brown) *D&C Brown No. 1.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Resorcin Brown", should be listed under the common name "D&C Brown No. 1", and the technical description appearing under the heading "Specifications" should read "Monosodium salt of 4-p-sulfophenylazo-2-(2, 4-xylylazo)-1,3-resorcinol". The specification "m-Xylidine, not more than 0.2%" is an intermediate used in the manufacture of this color and to the extent that it remains in the finished product, is an impurity. The tolerance stated can be met in good manufacturing practice. This color, with the remaining specifications in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 154, 318, 331; Government's Exhibit No. 1)

91

(Alizurol Purple SS) *D&C Blue No. 3.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Alizurol Purple SS," should be listed under the common name "D&C Blue No. 3," and the technical description appearing under the heading "Specifications" therein should read "1-Hydroxy-4-p-toluino-anthraquinone." The specification "p-Toluidine, not more than 0.2 percent," relates to an intermediate used in the manufacture of this color and to the extent that it remains in the finished product as an impurity. The tolerance stated can be met if good manufacturing practices are employed. This color, with the remaining specifications in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 155, 318, 331; Government's Exhibit No. 1)

92

(Alphazurine FG) *D&C Blue No. 4.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Alphazurine FG," should be listed under the common name "D&C Blue No. 4," and the technical description of the color appearing under the heading "Specifications" should appear as "Diammonium Salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl]-(2-sulfoniumphenyl)-methylene)-[1-(N-ethyl-N-p-sulfobenzyl)-$^{2}\Delta^{5}$-cyclohexadienimine]." The color, with the other specifications is found to be harmless and suitable for use in drugs and cosmetics. (R., p. 318; Government's Exhibit No. 1)

93

(Alizarin Astrol B) *D&C Blue No. 5.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Alizarin Astrol B", should be listed under the common name "D&C Blue No. 5", and the technical description appearing under the heading "Specifications" therein should read "Monosodium salt of 1-methylamino-4-(o-sulfo-p-toluino)-anthraquinone". This color, with the other specifications in said exhibit, is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 156, 318, 332; Government's Exhibit No. 1)

94

(Indigo (Synthetic)) *D&C Blue No. 6.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Indigo (Synthetic)" should be listed under the common name "D&C Blue No. 6", and the technical name of this color appearing under "Specifications" therein, should be "Indigotin". It is found that obviously a printer's error occurred in the specification for this color as set up in said exhibit, since the specification "Ether extracts, not more than 0.5%" appears twice. The specification that was omitted in the exhibit is "Sulfated ash, not more than 2.0%". The specification "Matter, insoluble in dichlorhydrin, not more than 1.0 percent" is one that has not previously been referred to in any finding with respect to any color. Since the color itself is soluble in dichlorhydrin, materials present in the color which do not dissolve in this solvent are impurities which should be limited to less than 1.0%. The color, with these changes and the remaining specifications is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 156, 318, 332; Government's Exhibit No. 1)

95

(Naphthol Blue Black) *D&C Black No. 1.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (b), as "Naphthol Blue Black" should be listed under the common name "D&C Black No. 1", and the technical name of this color under "Specifications" therein should read "Disodium salt of 8-amino-7-p-nitrophenylazo-2-phenylazo-1-naphthol-3, 6-disulfonic acid". The specification "p-Nitroaniline, not more than 0.2 percent" is an intermediate used in the manufacture of this color which becomes an impurity that should not be permitted to be present in amounts greater than 0.2 percent. The color, with the other specifications in said exhibit is found to be harmless and suitable for use in drugs and cosmetics. (R., pp. 157, 318, 333; Government's Exhibit No. 1)

96

Structural Amendment of Section 35.02 (b) and (c) Composite Specifications for Lakes of Each Group—New Group (c)—New Names and Designations—D&C

That because of the finding that all individual lakes that are listed in Government's Exhibit No. 1, Section 35.02 (b) and (c) should be consolidated so as to have master specifications that are a composite of all the specifications that have been set up under each of the said lakes as listed in said exhibit (see finding of fact 26), it is necessary to amend the structure of said section 35.02 of Government's Exhibit No. 1 so as to make a new subdivision for lakes in the place of paragraph (c) of said exhibit, such new subdivision which contains the lakes set up in paragraph (b) becoming paragraph (c) and so that paragraph (c) as set up in said exhibit will become paragraph (d) and the lakes that were in paragraph (c) of said exhibit will become paragraph (e). It is found that the lakes that were listed in paragraph (b) of said section 35.02 of said exhibit should be set up as hereinbefore stated in new subparagraph (c) which should read, in effect, as follows: "A batch of a straight color in the form of a lake named in the following list may be certified in accordance with the provisions of those regulations for use only in drugs and cosmetics if such batch conforms to the specifications herein set forth for such color. General specifications: A straight color shall be free from all impurities (other than those named in the specifications herein prescribed for such color) to the extent that such impurities can be avoided by good manufacturing practice. Lakes: Any lake may be made from the following: (1) Any straight color listed in subsection (a), or (b), or (2) the aluminum salt prepared from FD&C Green No. 1, FD&C Green No. 2, FD&C Green No. 3, FD&C Yellow No. 1, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 1, FD&C Red No. 2, FD&C Red No. 3, FD&C Orange No. 1, D&C Red No. 5, D&C Red No. 6, D&C Red No. 10, D&C Red No. 19, D&C Red No. 20, D&C Orange No. 8, D&C Orange No. 10, D&C Red No. 21, D&C Orange No. 4, D&C Blue No. 4, D&C Blue No. 6; the barium salt prepared from FD&C Green No. 1, FD&C Green No. 2, FD&C Green No. 3, FD&C Yellow No. 1, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 1, FD&C Red. No. 2, FD&C Orange No. 1, FD&C Blue No. 2, D&C Yellow No. 10, D&C Red No. 5, D&C Red No. 8, D&C Red No. 10, D&C Red No. 14, D&C Orange No. 4, D&C Blue No. 4; the zirconium salt prepared from FD&C Yellow No. 5; the calcium salt prepared from FD&C Red No. 2, D&C Red No. 5, D&C Red No. 6, D&C Red No. 14, D&C Orange No. 15; the calcium salt of D&C Red No. 31 (which is the calcium salt of 3-hydroxy-phenylazo-2-naphthoic acid) extended on alumina, blanc

fixe, gloss white, clay, titanium dioxide, zinc oxide, talc or aluminum benzoate, shall be considered to be individually listed for the purpose of this paragraph.

The name under which each lake shall be considered to be listed herein shall be formed as follows: (1) In the case of a straight color listed in subsection (a) or (b), the name under which such straight color is listed (except that in the case of colors listed in subsection (a), the symbol "FD&C" shall be replaced by the symbol "D&C"), or, in the case of a color, the salt of which is included in clause 2 of this paragraph, the name of the color from which the salt is formed (except that in the case of colors designated by the symbol "FD&C" this symbol shall be replaced by the symbol "D&C"); (2) the name of the metallic base chemically combined in the color; and (3) the word "lake" (for example, the name of a lake prepared from the color "D&C Red No. 9" extended upon a substratum would be "D&C Red No. 9—Barium Lake", and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum would be "D&C Green No. 1—Aluminum Lake"). "Specifications" (the technical description of each such lake shall be (1) the chemical name of the coal-tar color component of the lake, (2) the words "extended on" and (3) the name of the substratum upon which such coal-tar color component is extended.) Ether extracts, not more than 0.05 percent, soluble barium in dilute HCl (as $BaCl_2$) not more than 0.05 percent soluble chlorides and sulfates (as sodium salts) not more than 0.05 percent, lead (as Pb) not more than 0.002 percent, arsenic (as As_2O_3) not more than 0.0002 percent, heavy metals (except Pb and As) (by precipitation as sulfides) not more than 0.003 percent, intermediates not more than 0.2 percent." (R., pp. 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 604, 605, 606, 610; Government's Exhibit No. 1)

97

Structural Amendment of Section 35.02 (b) and (c) New Group (d)

That in Government's Exhibit No. 1, Section 35.02 (c), the following language appears: "A batch of a straight color named in the following list may be certified, in accordance with the provisions of these regulations, for use only in externally applied drugs and cosmetics if such batch conforms to the specifications herein set forth for such color. (Where a number follows the specification of identity, such number is the number assigned to such color in the Colour Index of 1924, published by the Society of Dyers and Colourists of England)." This subsection should be designated (d) instead of (c) and the language just quoted should be changed to read "A batch of a straight color named in the following list may be certified, in accordance with the provisions of these regulations, for use only in externally applied drugs and cosmetics if such batch conforms to the specifications herein set forth for such color." The change in letter assigned to this subsection is made necessary in consolidation of lakes harmless for use in drugs and cosmetics into a separate specification (R., pp. 162, 338, 339, 606, 609, 611; Government's Exhibit No. 1)

98

(Metanil Yellow) *Ext D&C Yellow No. 1.* That the common name of a color as listed in Government's Exhibit No. 1, Section 35.02 (c), as "Metanil Yellow", should be listed under the common name "Ext D&C Yellow No. 1", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Monosodium salt of 4-m-sulfophenylazo-diphenylamine". The specification therein of "Chloroform soluble matter, not more than 0.5 percent" has not previously been referred to in any previous finding. This specification should be included because chloroform soluble matter is a measure of uncombined intermediates; that these intermediates cannot be entirely eliminated but the tolerance can be met if good manufacturing practice is followed. Another specification not previously referred to with respect to any color is "Diphenylamine, not more than 0.2 percent". This specification is one of the intermediates used in the manufacture of this color and should be limited to not more than 0.2 percent. If good commercial practice is followed, this limit can readily be made. This color, with the specifications in said exhibit, and the said change in the technical description, is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 157, 318, 334; Government's Exhibit No. 1)

99

(Metanil Yellow CA) *Ext D&C Yellow No. 2.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Metanil Yellow CA" should be listed under the common name "Ext D&C Yellow No. 2", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Calcium salt of 4-m-sulfophenylazo-diphenylamine". Its specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 158, 318, 334; Government's Exhibit No. 1)

100

(Fast Light Yellow) *Ext D&C Yellow No. 3.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c) as "Fast Light Yellow" should be listed under the common name "Ext D&C Yellow No. 3", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Monosodium salt of 5-hydroxy-3-methyl-4-phenylazo-1-p-sulfophenyl-pyrazole". Its specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 158, 318; Government's Exhibit No. 1)

101

(Polar Yellow 5 G) *Ext D&C Yellow 4.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c) as "Polar Yellow 5G" should be listed under the common name "Ext D&C Yellow No. 4", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Monosodium salt of 1-(4-chloro-o- sulfophenyl)-5-hydroxy-3-methyl-4-[p-(p-tolysulfonoxy)-phenyl-azo]-pyrazole". The specification "p-Aminophenol, not more than 0.2 percent" has not previously been referred to in connection with any other color. This substance is an intermediate used in the manufacture of this color and since it is an impurity when present in the finished product, its presence should be restricted to not more than 0.2%. The remaining specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 158, 159, 318, 335; Government's Exhibit No. 1)

102

(Amidonaphthol Red 6B) *Ext D&C Red No. 1.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c) as "Amidonaphthol red 6B" should be listed under the common name "Ext D&C Red No. 1", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Disodium salt of 8-acetamido-2-p-acetamidophenylazo-1-naphthol-3,6-disulphonic acid". The specification "p-Amino acetanilid, not more than 0.2 percent" has not previously been referred to with respect to any other color. This is an intermediate used in the manufacture of the color and the above limit can be met in good manufacturing practice. The remaining specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 159, 318, 335; Government's Exhibit No. 1)

103

(Pigment Scarlet NA) *Ext D&C Red No. 2.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Pigment Scarlet NA" should be listed under the common name "Ext D&C Red No. 2", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Trisodium salt of 1-o-carboxyphenylazo-2-naphthol-3,6-disulfonic acid". Its spec-

ifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R. pp. 159, 318, 336; Government's Exhibit No. 1)

104

(Violamine R) *Ext D&C Red No. 3.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Violamine R" should be listed under the common name "Ext D&C Red No. 3", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Diosodium salt of 9-o-carboxyphenyl-6-(4-sulfo-o-toluino) -3 -o- tolylimino - 3 - isoxanthene". Its specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 159, 318, 336; Government's Exhibit No. 1)

105

(Dichlorotetraiodofluorescein) *Ext D&C Red No. 4.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Dichlorotetraiodofluorescein" should be listed under the common name "Ext D&C Red No. 4", and the technical description of this color appearing under the heading "Specifications" therein should appear as "12,15 - dichloro - 2 - 4,5,7 - tetraiodo - 3,6 - fluorandiol". Its specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be suitable and harmless for use in externally applied drugs and cosmetics. (R., pp. 160, 318, 336; Government's Exhibit No. 1)

106

(Rose Bengale TD) *Ext D&C Red No. 5.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Rose Bengale TD" should be listed under the common name "Ext D&C Red No. 5", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Disodium salt of 9-(3,6 - dichloro - o - carboxyphenyl) - 6 - hydroxy - 2,4,5,7 - tetraiodo - 3 - isoxanthone". Its specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 160, 318, 336; Government's Exhibit No. 1)

107

(Rose Bengale TDK) *Ext D&C Red No. 6.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Rose Bengale TDK" should be listed under the common name "Ext D&C Red No. 6", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Dipotassium salt of 9-(3,6-dichloro-o-carboxyphenyl) - 6 - hydroxy - 2,4,5,7-tetraiodo-3-isoxanthone". Its specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 160, 318, 336; Government's Exhibit No. 1)

108

(Alizarin Carmine) *Ext D&C Red No. 7.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Alizarin Carmine" should be listed under the common name "Ext D&C Red No. 7", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Monosodium salt of 3,4-dihydroxy-2-anthraquinonesulfonic acid". The specification "Free acid as H_2SO_4, not more than 0.01 percent" has not previously been referred to in any preceding finding of fact, with respect to any of the other colors. This color very often contains free acid and the acid content should be limited to 0.01 percent. Manufacturers can meet this tolerance. The remaining specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 160, 318, 336; Government's Exhibit No. 1)

109

(Methylene Blue) *Ext D&C Blue No. 1.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Methylene Blue" should be listed under the common name "Ext D&C Blue No. 1", and the technical description of this color appearing under the heading "Specifications" therein should appear as "3-methochloride of 9 - dimethylamino-3-methylimino-3-isophenothiazine." The specification "Dimethyl aniline, not more than 0.2 percent", not previously referred to in connection with any other colors, is with respect to an intermediate that is used in the manufacture of this color. The impurity in the form of the intermediate cannot be completely eliminated but if good manufacturing practices are followed, the limit above stated can be met. The remaining specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 161, 318, 337; Government's Exhibit No. 1)

110

(Methylene Blue-Zinc Double Chloride) *Ext D&C Blue No. 2.* That the common name of a color listed in Government's Exhibit No. 1, Section 35.02 (c), as "Methylene Blue—Zinc Double Chloride" should be listed under the common name "Ext D&C Blue No. 2", and the technical description of this color appearing under the heading "Specifications" therein should appear as "Zinc chloride double salt of 3-methochloride of 9-dimethylamino-3-methylimino-3-isophenothiazine". The specification "Zinc chloride (not a part of the dye), not more than 1.0 percent" has not previously been referred to with respect to any preceding color. A certain amount of zinc chloride is a part of the dye itself. However, excessive amounts not chemically combined in the dye should not be present, and the limit proposed is one that can be met in good manufacturing practice. The remaining specifications are all found to be appropriate as they appear in said exhibit; and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics. (R., pp. 161, 318, 337; Government's Exhibit No. 1)

111

Structural Amendment of Section 35.02 (a) and (b) Composite Specifications For Lakes—New Group (e)—New Names and Designations—Ext D&C

That all of the individual lakes that are listed in Government's Exhibit No. 1; Section 35.02 (c) all of which are harmless and suitable for use in externally applied drugs and cosmetics, when consolidated so as to have master specifications that will be a composite of all of the specifications that have been set up under each of said lakes listed in said subsection, will require a new subsection to be designated "35.02 (e)," in which said new subsection it is found that a batch of a straight color in the form of lakes named in the following list may be certified in accordance with the provisions applicable to certification for use only in externally applied drugs and cosmetics if such batch conforms to the specifications hereinafter set forth for the color. These lakes, which are straight colors, should be free from all impurities (other than those named in the specifications hereinafter prescribed) to the extent that such impurities can be avoided by good manufacturing practice, it is found that any lake to be entitled to listing in the aforesaid subsection (e) may be made from the following:

(1) Any straight color listed in subsection (d), or

(2) The aluminum salt prepared from Ext D&C Yellow No. 1, Ext D&C Yellow No. 3;

The barium salt prepared from Ext D&C Yellow No. 3, Ext D&C Red No. 2;

The calcium salt prepared from Ext D&C Red No. 2,

extended on alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, or aluminum benzoate, shall be considered to be individually listed for the purpose of said subsection. The name under which each such lake shall

be considered to be so listed shall be formed as follows:

First, in the case of a straight color listed in subsection (d) the name under which such straight color is listed, or in the case of a color the salt of which is included in clause (2) of paragraph (e) the name of the color from which the salt is formed;

Second, the name of the metallic base chemically combined in the color; and

Third, the word "lake."

The specifications for said lakes shall be as follows:

The technical description of each lake shall be:

(1) the chemical name of the coal-tar color component of the lake

(2) the words "extended on", and

(3) the name of the substratum upon which such coal-tar color component is extended; ether extracts, not more than 0.5 percent; soluble barium (in dilute HCl) (as $BaCl_2$), not more than 0.05 percent; soluble chlorides and sulfates (as sodium salts), not more than 5.0 percent; lead (as Pb), not more than 0.002 percent; arsenic (as AS_2O_3), not more than 0.0002 percent; heavy metals (except Pb and As) (by precipitation as sulphides), not more than 0.003 percent; intermediates, not more than 0.2 percent.

It is found that lakes made according to the preceding specifications are harmless and suitable for use in externally applied drugs and cosmetics. (R. pp. 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 604, 605, 606, 610. Government's Exhibit No. 1)

112

Mixtures Which May Be Certified

It is found that the matters and things set forth in Section 35.03 of Government's Exhibit No. 1, relating to mixtures which may be certified, are factually true and administratively desirable subject to certain changes arising because of the new grouping of lakes hereinbefore referred to in previous findings of fact, whereby paragraph (b) of Section 35.02 of said Government's Exhibit No. 1 becomes paragraphs (b) and (c) and paragraph (c) becomes paragraphs (d) and (e). It is found that a batch of a mixture which contains no straight color listed in Section 35.02 of said exhibit (b) or (c), as amended, as aforesaid, should be certified in accordance with the provisions relating to certification for use in foods, drugs, and cosmetics if each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture, or if each diluent in such batch of mixture is harmless and suitable for use therein, or if no diluent (except resins, natural gum, and pectin) in such mixture is a nonnutritive substance, unless such mixture is used for coloring a food specified in the request for certification of such batch submitted in accordance with Section 35.05 (c) of Government's Exhibit No. 1, amended, as aforesaid, and such diluent in the usual process of manufacturing such food is removed and does not become a component of such food.

It is found that a batch of a mixture should be certified for use in foods, drugs, and cosmetics if it contains no straight color listed in Section 35.02 (b) or (c) of Government's Exhibit No. 1, as amended, as aforesaid, and if each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture.

It is found that if diluents are used in making these mixtures said diluents should be harmless and suitable for use. It is further found that no diluents (other than resins, natural gum, and pectin) should be used in such mixtures if the diluent is a nonnutritive substance. The only exception to this requirement is that nonnutritive diluents should be permitted for use in a color mixture which is intended to be used in coloring food, if in the process of coloring the food product the nonnutritive diluent does not become a part of the food which is colored but is removed.

It is found that a batch of a mixture which contains no straight color listed in Section 35.02 (c) of Government's Exhibit No. 1, as amended, as aforesaid, or which does not contain a diluent not permitted by clause (3) of paragraph (a) or which does contain a nonnutritive ingredient should be certified for use in any drugs and cosmetics if each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and the color is not changed in composition, except such change as may be caused by the mixing and that it should also be required that each diluent in the batch is harmless and suitable for use therein.

It is also found that mixtures of coal-tar colors which are listed in Section 35.02 (c) of Government's Exhibit No. 1, as amended, as aforesaid, should be certified for use in externally applied drugs and cosmetics, if each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and if the color previously certified has not changed in composition in any manner whatsoever since such previous certification, except by mixing into such batch of mixture. It should also be required that each diluent in such batch of mixture should be harmless and suitable for use therein.

With respect to this finding of fact, it is reiterated that paragraph (b) of Section 35.02 of Government's Exhibit No. 1, becomes paragraphs (b) and (c) and paragraph (c) becomes paragraphs (d) and (e), this constituting the amendment hereinbefore referred to. (R., pp. 82, 340, 341, 342, 343; Government's Exhibit No. 1)

113

Sampling, Storage, and Packaging

It is found that the matters and things set forth in Section 35.04 of Government's Exhibit No. 1 are factually correct and administratively necessary, subject to the corrections hereinafter set forth. It is found that administrative procedure that should be followed in the sampling, storage, and packaging of coal-tar colors for certification is that samples be submitted by a person who seeks certification of a batch of coal-tar color, which sample should be taken from the batch sought to be certified after the batch has been so thoroughly mixed as to be of uniform composition throughout. It is found that to preserve the integrity of the sample immediately after it is taken it should be so packaged as to prevent changes in composition and the package containing the sample should be labeled in a conspicuous manner so as to show the name and post office address of the person who submitted the request, the name of such color, the batch number, and the quantity of such batch. Immediately after the sample is taken, the batch should be stored in containers which will prevent changes in the composition of the color, or the batch should be closed in packages for shipment or delivery and held in such condition until the batch either is certified or certification thereof is refused. If the batch is certified and at the time of the certification the batch or any part of it is stored, the storage should be maintained until the batch is either closed in packages for shipment in such a way as to prevent changes in composition or is used by the person who obtained the certificate as an ingredient in a batch of a mixture on which such person submits a request for certification, or until the batch is used by the person who requested certification in coloring a food, drug, or cosmetic, in accordance with the restricted uses for which the batch was certified. Requirements should be made that packages in which coal-tar colors are enclosed for shipment or delivery should be of such kind as to prevent changes in composition of the color and should be so closed or sealed that the package cannot be opened without destroying the package or its seal. In Section 35.04 (d) of Government's Exhibit No. 1 the parenthetical statement "(except for the purpose of stating the percentage of pure dye as required by Section 35.08 (a) (3) and (b))" appears. This statement should be deleted as the percentage of pure dye referred to should be the percentage of pure dye stated by the Food and Drug Administration in its certificate covering such batch. It is found that unavoidable changes in the moisture content of a coal-tar color which

occur even through good commercial practice in storing, packing, and distributing the color should not be considered to be a change in its composition. (R., pp. 21, 22, 23, 24, 37, 38, 70, 71, 72, 170; Government's Exhibit No. 1)

114

Requests for Certification

It is found that Section 35.05 of Government's Exhibit No. 1 is factually accurate and administratively necessary. When an application for certification is received from a foreign manufacturer, the application should be filed jointly by the manufacturer and his agent in the United States. A person who requests certification of a batch of a straight color should be required to submit as a part of the request, first, a statement showing whether or not he manufactured the batch, and if he did not, the name and post office address of the manufacturer, and, second, the name of such straight color as listed in the regulations finally promulgated, and the batch number and the quantity of such batch. It is found that a sample of one-half pound of such straight color is necessary for analysis, that the sample should be accurately representative of the batch from which it is taken, and that the fee for the certification of such batch should accompany the request. It is further found that any additional information or samples which the Food and Drug Administration may require to determine whether or not the batch complies with the requirements for the issuance of a certificate, should be made available upon the request of said administration. A person who applies for the certification of a batch of a mixture containing coal-tar color should submit a statement showing that he mixed such batch, the name of such mixture, the batch number, and the quantity of such batch. At the same time that a person requests certification of a batch of a mixture, he should submit information to the Food and Drug Administration showing lot numbers of the certified colors that were used and the amounts used, and that such colors have not changed in composition since certification, except such change as was incident to mixing into the batch. The name, quantity and quality of each diluent used in the preparation of a mixture should be stated by the person who applies for certification of a mixture. In the event the mixture contains nonnutritive substances other than rosins, natural gum, and pectin, which are to be permitted in coal-tar colors used for coloring foods only because the nonnutritive substance does not become a component of the food, the name of the food in which such color is used should be specified. A person who submits a request for certification of a mixture must affirmatively assure the Food and Drug Administration that the batch of color from which the sample was taken has been very effectively mixed and should fully describe the process of mixing and make special reference to the precautions taken to render the batch uniform. A one-fourth pound sample is found to be sufficient to represent accurately a batch from which it is taken and such a sample should be submitted together with tender of payment of whatever fee is required. Such further samples and information as the Food and Drug Administration may require for the purpose of determining whether or not such mixed batch complies with the specifications and regulations should be required to be submitted. A person who requests certification of a batch made by repacking a coal-tar color from a batch previously certified should submit as a part of his request, first, statements to the effect that he made the batch on which he requests certification by repacking such color, and that such color has not changed in composition in any manner whatever since such previous certification; second, the person who requests certification of a batch made by repacking a coal-tar color from a batch previously certified should submit as a part of his request information showing the name, quantity, and lot number of the repacked color and the batch number and quantity of such repacked batch; that he should also submit a sample consisting of one-fourth pound, accurately representative of the batch, and that the fee prescribed should accompany the request. Additional samples and additional information should be made available to the Food and Drug Administration upon request. (R., pp. 25, 26, 27, 28, 29, 45, 68, 71, 72, 73, 74, 82, 84, 85, 86, 167, 340, 342; Government's Exhibit No. 1)

115

Certification

It is found that Section 35.06 of Government's Exhibit No. 1, as set forth in said exhibit, is factually correct and administratively necessary. That the Food and Drug Administration should issue a certificate to the person who submits a request for certification of straight coal-tar colors and mixtures of coal-tar colors, if after such investigation as the Food and Drug Administration determines to be necessary, it is found that the request appears to contain no untrue statement of any material fact. That in the case of a straight color it conforms to the specifications set forth herein, and in the case of a mixture containing a diluent, the diluent is harmless and suitable for use therein, and that the batch covered by such request otherwise appears to comply with the regulations as promulgated. It is found that the certificates to be issued by the Food and Drug Administration should show the lot number assigned to the batch, the percentage of pure dye as determined by analysis, and that such batch, subject to the terms, conditions and restrictions prescribed hereinafter, should thus become a certified batch for use in food, drugs and cosmetics, or for use only in drugs and cosmetics, or for use only in externally applied drugs and cosmetics. It is further found that if the Food and Drug Administration finds after such reasonable investigation as may be considered necessary that a request for certification of a batch of coal-tar color dealt with in such request does not comply with the requirements to which reference has been made for the issuance of a certificate, the Food and Drug Administration should refuse to certify such batch and they should give notice to the person who submitted the request stating the reasons for refusing to issue a certificate. (R., pp. 30, 31, 74, 75, 76, 341; Government's Exhibit No. 1)

116

Limitations of Certificates

It is found that the matters and things set forth in Section 35.07 of Government's Exhibit No. 1 are factually true and administratively necessary. If a certificate is issued upon a misrepresentation of a material fact, such certificate should not be effective, and the color should be considered to be from a batch that has not been certified. If between the time a sample from a batch of coal-tar color is submitted with a request for certification and the time the certificate is issued the batch changes in composition, the certificate should not be effective and the color from such batch should be considered to be from a batch that has not been certified. If at any time after a certificate is received by the person to whom it is issued any color from the batch covered by the certificate becomes changed in composition in any manner, the certificate should expire with respect to such changed color and the color should thenceforth be considered as from a batch that has not been certified, except that if the only change in the color is incident to the use of the batch, or a portion of it, in preparing a batch of a mixture for certification as a mixture, the change in composition of the color resulting from such mixing should not cause the color to become an uncertified color. Any certificate that may be issued should expire if the package in which the certified color is closed for shipment or delivery is opened, except when such opening is solely for the purpose of repacking by the person to whom the certificate was issued; and after such expiration such color should be considered to be from a batch which has not been certified. An exception, however, should be made when colors certified for use in foods, drugs, and cosmetics, are used in coloring foods, drugs, and cosmetics, when coal-tar colors certified for use in drugs and cosmetics are used in coloring drugs and cosmetics, and when coal-tar colors certified for use in externally applied drugs and cosmetics are used for these restricted purposes. The lot

should also not be considered an uncertified color if the package is opened for the sole purpose of certifying a batch made by repacking such color or for the purpose of certifying a batch of a mixture in which the previously certified color is used as an ingredient. A certificate should not be effective with respect to a package of coal-tar color and such color should be considered to be from a batch that has not been certified if such package is shipped or delivered under a label which does not comply in all respects with the requirements concerning labeling hereinafter set forth. If a mixture from a batch containing a nonnutritive ingredient is certified only for use in a particular food because the diluent does not become a part of such food color by such mixture and such mixture is in fact used in coloring some other food, the mixture should be considered to be from a batch that has not been certified. If a coal-tar color is certified for any restricted use and is used in foods, drugs, or cosmetics, in any way other than as contemplated in the restrictions imposed, such coal-tar color should be considered to be from a batch that has not been certified. (R., pp. 31, 32, 33, 75, 82, 341; Government's Exhibit No. 1)

117

Labeling

That the matters and things set forth in Section 35.08 of Government's Exhibit No. 1 are factually correct and administratively necessary. It is found that the label of each package of coal-tar color from a batch that has been certified should bear all words, statements and information required by, or under authority of the Food, Drug, and Cosmetic Act of 1938, as well as the name of such color. The lot number assigned to such batch by the Food and Drug Administration at the time such batch was certified, the percentage of pure dye which is found by chemical analysis by the Food and Drug Administration to be present in such color, and in the case of coal-tar colors, certified for use in drugs and cosmetics, the statement "Not for use in coloring foods", and that those certified for use in externally applied drugs and cosmetics, should bear the label statement "Not for use in coloring food, or in coloring any drug or cosmetic used internally, or on the lips or any mucous membrane". If a batch of such color is a mixture containing a nonnutritive ingredient permitted only because such nonnutritive ingredient does not become a component of the food colored by such mixture, the label should bear the statement "Not for use in coloring any food except _____", (the blank to be filled in by the name of such food). In said section 35.03 in said exhibit, paragraph (b), appears "The statement of the percentage of pure dye in a coal-tar color shall express the minimum percentage by weight. No variation below the stated minimum shall be permitted; variations above shall not be unreasonably large, but shall allow for unavoidable absorption of moisture by such color caused by ordinary and customary exposure that occurs in good storage, packing, and distribution practice." The statement of the percentage of pure dye in a coal-tar color should be stated upon the label and should express the minimum percentage by weight. However, it is found that the above-quoted statement should not be incorporated in the regulations since the percentage of pure dye, for the purposes of the declaration upon the label referred to, should be the percentage of pure dye stated in the certification of such color issued by the Food and Drug Administration. It is found that the label of a certified straight color should state the name by which such color is listed. It is further found that no batch of a mixture should be certified if the name of such mixture is false or misleading in any particular, or the name of the mixture is the same as or simulates the name of a previously certified batch of a mixture containing a different substance or a different percentage of a pure dye, but that this requirement should not apply if the person who requests the certification of such batch is the owner of such name and has given three months' written notice to the Food and Drug Administration, specifying the change to be made in the composition of the mixture. (R., pp. 35, 37, 78, 79, 170, 171; Government's Exhibit No. 1)

118

Records of Distribution

That the matters and things set forth in Section 35.09 of Government's Exhibit No. 1 are found to be factually correct and administratively necessary. It is found that the person to whom a certificate is issued should keep a complete record showing the disposition of all coal-tar color of a batch covered by the certification; that he shall make this information readily available upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States acting on behalf of the Secretary of Agriculture, at all reasonable hours until at least one year after disposal of all such color. That such officer or employee should also be given full opportunity to make inventories of stocks of such color on hand and otherwise to check the correctness and completeness of such records. Records required to be kept should consist of

(1) Records showing each quantity used by the person who obtained a certificate from the batch and the date and time of such use; and

(2) The date and quantity of each shipment or delivery from each such batch, and the name and post office address of the person to whom such shipment or delivery was made. (R., pp. 40, 41, 42, 77, 78, 79, 80; Government's Exhibit No. 1)

119

Authority to Refuse Certification Service

That the matters and things set forth in Section 35.10 of Government's Exhibit No. 1 are found to be factually correct and administratively necessary. It is found that the Secretary of Agriculture should suspend immediately further certification service to any person who obtained a certificate through fraud or misrepresentation of a material fact or who falsified the records found to be essential to the maintenance of an effective certification system or who fails to keep such records or to make available to an officer or employee of the Food and Drug Administration or to any other officer or employee of the United States acting on behalf of the Secretary of Agriculture or who fails fully to accord to the officials opportunities to make inventories of stocks on hand, or otherwise to check the correctness and completeness of such records as are necessary. Such suspension should continue unless and until such person shows adequate cause why the suspension should be terminated. (R., pp. 41, 42, 76; Government's Exhibit No. 1)

120

Procedure for Admitting Colors to Listing

That the matters and things that appear in Section 35.11 of Government's Exhibit No. 1 are found to be factually correct and administratively necessary. Each application for the admission of any coal-tar color to listing, which said color has not previously been listed, should be accompanied by

(1) Full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in foods, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

(2) A full statement of the percentages and compositions of the pure dye and all intermediates and other impurities contained in such color;

(3) A full statement showing the identity, purity, and quantity, or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) A full description of practical and accurate methods of analysis for the quantitative determination of pure dye and all intermediates and other impurities contained in such color;

(5) A full description of practical and accurate methods for the identification of such dye in foods, drugs, and cosmetics, colored therewith, or in drugs and cosmetics colored therewith;

(6) A five-pound sample of such color (unless the Food and Drug Administration authorizes or requires submission of other quantity suitable to the need for

investigation) taken from a batch produced under practical manufacturing conditions, and accurately representative of such batch; and

(7) Whatever advance deposit is required in the regulations.

It is found that the Secretary of Agriculture should determine after such investigation as he considers to be necessary that

(1) Such color is harmless and suitable for use in foods, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics;

(2) Practical and accurate methods of analysis exist for the quantitative determination of the pure dye and all intermediates and other impurities contained in such color; and

(3) Practical and accurate methods exist for the identification of such dye in foods, drugs, and cosmetics, colored therewith, or in drugs and cosmetics colored therewith. It is found that when information as above specified is submitted, the Secretary of Agriculture should, for the purpose of listing such color, proceed in the manner required for a proposed amendment to the regulations as set up in Section 701 (e) of the Federal Food, Drug, and Cosmetic Act. It is further found that the Secretary of Agriculture, after such investigation as may be considered necessary, determines that any color does not comply with the said requirements with respect to the procedure for the listing of coal-tar colors for certification, the Secretary of Agriculture should give notice thereof to the applicant, stating the respects in which such color does not so comply. (R., pp. 42, 43, 81, 82; Government's Exhibit No. 1)

121

Fees

That the matters and things set forth in Government's Exhibit No. 1, Section 35.12, are found to be factually correct and administratively necessary. It is found that the fee for the certification of a batch of straight color should be $15; that the fee for the certification of a batch of a mixture or of a repacked batch of a previously certified coal-tar color should be $8. The fee for the addition of a coal-tar color to those listed for certification should be the cost incurred by the Secretary of Agriculture in making such investigations as he may determine to be necessary. An application for the listing of a coal-tar color should be accompanied by an advance deposit of $500 to cover the cost of the investigations and subsequent advance deposits of the same amount or of different amounts should be made if the Food and Drug Administration authorizes a deposit of another amount, or whenever necessary to prevent arrears in the payment of a fee. It is found that if any excess advance deposit is made, the same should be returned to the applicant after the close of the investigation which the Food and Drug Administration may determine to be essential. It is further found that all fees and deposits required to be paid should be paid by money order, bank draft, or certified check, drawn to the order of the Treasurer of the United States, collectible at par at Washington, D. C., and that all earned fees should be deposited in the Treasury of the United States to the credit of Miscellaneous Receipts, Department of Agriculture. (R., pp. 43, 44, 45, 81; Government's Exhibit No. 1)

122

Colors Listed in 35.02 (a), (b), (c), (d), and (e) May Be Certified for Purposes Indicated

That all of the straight colors listed in Government's Exhibit No. 1, Section 35.02, including lakes, with the specifications therefor, that were set up in said exhibit, and with the names and specifications thereof changed and amended as appears in the preceding findings of fact, as hereinbefore found necessary because of substantial evidence received at said hearing, have each and every one of them been examined and approved by chemists and pharmacologists of the Food and Drug Administration, United States Department of Agriculture, and have been found by said chemists and pharmacologists to be harmless and suitable for the uses described in said section 35.02 of said exhibit, when the text of said section of said exhibit is amended in the manner found to be necessary in the findings of fact preceding this finding of fact; that the said colors so named and tested, and all of them, are hereby found to be harmless and suitable for such uses, namely: the colors listed in paragraph (a) of said section of said exhibit, in the identities established by the preceding finding of fact, are found to be harmless and suitable for use in foods, drugs, and cosmetics; the colors listed in paragraph (b) of said section of said exhibit, in the identities established by the preceding finding of fact, are found to be harmless and suitable for use in drugs and cosmetics; the colors in the form of lakes, in the identities established by the preceding finding of fact, which said lakes it has been found should be deleted from said section (b) and placed in a new section (c), are found to be harmless and suitable for use in drugs and cosmetics; the colors listed in paragraph (c) of said section of said exhibit, which said paragraph (c) should be changed to paragraph (d), in the identities established by the preceding finding of fact, are found to be harmless and suitable for use in externally applied drugs and cosmetics. The colors in the form of lakes, in the identities established by the preceding finding of fact, which said lakes it has been found should be deleted from said section (c) of said exhibit and placed in a new section (e) are found to be harmless and suitable for use in externally applied drugs and cosmetics; and batches of such colors, including the said lakes, are found to be entitled to be listed under the subdivisions just named in the regulations to be promulgated providing for the listing of coal-tar colors which are harmless and suitable for use in foods, drugs, and cosmetics under the Federal Food, Drug, and Cosmetic Act in order that said colors may be certified by the Secretary of Agriculture for the purposes aforesaid. (R., pp. 106, 242, 96, 97, 240, 314, 318; Government's Exhibit No. 1)

Conclusions

Based upon the foregoing findings of fact, it is concluded that the regulations hereinafter set forth should be promulgated.

Regulations Under the Federal Food, Drug, and Cosmetic Act

REGULATIONS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT FOR THE LISTING OF COAL-TAR COLORS, CERTIFICATION OF BATCHES THEREOF, AND PAYMENT OF FEES FOR SUCH SERVICE

SEC. 135.01 *Definitions.* For the purposes of these regulations—

(a) The term "coal-tar color" means articles which (1) are composed of or contain any substance derived from coal-tar, or any substance so related in its chemical structure to a constituent of coal-tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, cosmetic, or the human body or any part thereof, are capable (alone or through reaction with other substance) of imparting color thereto.

(b) The term "straight color" means a coal-tar color listed in Section 135.03, 135.04, or 135.05, and includes such impurities and substrata as are contained in such color.

(c) The term "mixture" means a coal-tar color made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(d) The term "diluent" means any component of a coal-tar color, except a straight color.

(e) The term "pure dye" means the coal-tar dye contained in a coal-tar color, exclusive of any intermediate or other impurity, or of any diluent or substratum contained therein.

(f) The term "substratum" means the substance on which the pure dye in a lake is extended.

(g) The term "alumina" means a suspension in water of precipitated aluminum hydroxide.

(h) The term "blanc fixe" means a suspension in water of precipitated barium sulfate.

(i) The term "gloss white" means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term "mixed oxides" means the sum of the quantities of aluminum,

iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum oxide, ferric oxide, calcium oxide, and magnesium oxide.

(k) The term "batch" means a quantity of coal-tar color which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(l) The term "batch number" means the number assigned to a batch by the person who requests certification thereof.

(m) The term "lot number" means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(n) The term "externally applied drugs and cosmetics" means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o) The authorization contained in these regulations for the certification of coal-tar colors shall not be considered to authorize the certification of any coal-tar color for use in any article which is applied to the area of the eye. A coal-tar color used in any such article which is so applied shall be considered to be from a batch that has not been certified in accordance with these regulations, even though such color is from a batch that has been certified for other use.

(p) The term "area of the eye" means the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(q) The definitions and interpretations of terms contained in section 201 of the Act shall be applicable also to such terms when used in these regulations.

SEC. 135.02 *General specification for straight colors.* No batch of a straight color listed in section 135.03, 135.04, or 135.05 shall be certified under these regulations unless—

(a) It is free from all impurities (other than those named in paragraph (b) or in the specifications set forth in such section for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in section 135.03—

Lead (as Pb), not more than 0.001 percent.

Arsenic (as As_2O_3), not more than 0.00014 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in section 135.04 or 135.05—

Lead (as Pb), not more than 0.002 percent.

Arsenic (as As_2O_3), not more than 0.0002 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in section 135.04 or 135.05—soluble barium (in dilute HCl) (as $BaCl_2$), not more than 0.05 percent.

SEC. 135.03 *List of straight colors and specifications for their certification for use in food, drugs, and cosmetics.* A batch of a straight color listed herein may be certified, in accordance with the provisions of these regulations, for use in food, drugs, and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specifications herein set forth for such color.

FD&C Green No. 1

Specifications

Monosodium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)-diphenylmethylene]-[1-(N-ethyl-N-p-sulfoniumbenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

FD&C Green No. 2

Specifications

Disodium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl]-(4-sulfoniumphenyl)-methylene)-[1-(N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes (as Guinea Green B) not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

FD&C Green No. 3

Specifications

Disodium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl]-(4-hydroxy-2-sulfoniumphenyl)-methylene)-[1-(N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 1

Specifications

Disodium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 2

Specifications

Dipotassium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 3

Specifications

1-Phenylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 99° C.

FD&C Yellow No. 4

Specifications

1-o-Tolylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 120° C.

FD&C Yellow No. 5

Specifications

Trisodium salt of 3-carboxy-5-hydroxy-1-p-sulfophenyl-4- p -sulfophenylazo-pyrazole.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.3 percent.

Phenylhydrazine-p-sulfonic acid, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 3.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 6

Specifications

Disodium salt of 1-p-sulfophenylazo-2-naphthol-6-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Red No. 1

Specifications

Disodium salt of 1-pseudocumylazo-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

Pseudo-cumidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Lower sulfonated dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Boiling range of crude pseudo-cumidine, or of pseudo-cumidine obtained by reduction of the dye, 220–245° C.

FD&C Red No. 2

Specifications

Trisodium salt of 1-(4-sulfo-1-naphthylazo)-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more that 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 4.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Red No. 3

Specifications

Disodium salt of 9-o-carboxyphenyl-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 12.0 percent.

Water insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Sodium carbonate, not more than 0.5 percent.

Sodium iodide, not more than 0.4 percent.

Mixed oxides, not more than 1.0 percent.

Permitted range of organically combined iodine in pure dye, free from water of crystallization, 56.8 to 58.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

FD&C Red No. 4

Specifications

Disodium salt of 2-(5-sulfo-2,4-xylylazo)-1-naphthol-4-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Orange No. 1

Specifications

Monosodium salt of 4-p-sulfophenylazo-1-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent, alpha-Naphthol, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Mixed oxides, not more than 1.0 percent.

Orange II, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Orange No. 2

Specifications

1-o-Tolylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

o-Toluidine, not more than 0.05 percent.

beta-Naphthol, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 98.0 percent.

Melting point, not less than 128.0° C.

FD&C Blue No. 1

Specifications

Disodium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl] - (2-sulfoniumphenyl)-methylene)-[1-(N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Sodium acetate, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

FD&C Blue No. 2

Specifications

Disodium salt of 5,5′ indigotindisulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 7.0 percent.

Mixed oxides, not more than 1.0 percent.

Lower sulfonated dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

SEC. 135.04 *List of straight colors and specifications for their certification for use in drugs and cosmetics.*—(a) A batch of a straight color listed herein may be certified, in accordance with the provisions of these regulations, for use only in drugs and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specifications herein set forth for such color.

D&C Green No. 4

Specifications

Calcium salt of 4-([4-(N-ethyl-p-sulfobenzylamino) - phenyl] - (4 - sulfoniumphenyl) - methylene) - [1 - (N -ethyl-N - p - sulfobenzyl) - $\Delta^{2,5}$ - cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Subsidiary dyes (as FD&C Green No. 1), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Green No. 5

Specifications

Disodium salt of 1,4-bis(o-sulfo-p-toluine)-anthraquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

1,4 - Dihydroxy - anthraquinone not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 15.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 75.0 percent.

D&C Green No. 6

Specifications

1,4-Bis (p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 1.5 percent.

Intermediates, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

Melting point, not less than 210° C.

D&C Yellow No. 7

Specifications

3,6-Fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

D&C Yellow No. 8

Specifications

Disodium salt 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Yellow No. 9

Specifications

Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Yellow No. 10

Specifications

Disodium salt of disulfonic acid of 2-(2-quinolyl)-1,3-indandione.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Quinaldine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 82.0 percent.

D&C Red No. 5

Specifications

Disodium salt of 1-xylylazo-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 12.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Xylidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Red No. 6

Specifications

Monosodium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Red No. 7

Specifications

Calcium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 8.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates (as calcium salts), not more than 6.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Red No. 8

Specifications

Monosodium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Lake Red C Amine, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Red No. 9

Specifications

Barium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Lake Red C Amine, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 87.0 percent.

D&C Red No. 10

Specifications

Monosodium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 11

Specifications

Calcium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 12

Specifications

Barium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 13

Specifications

Strontium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 14

Specifications

Monosodium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 15

Specifications

Barium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 16

Specifications

Calcium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 17

Specifications

1-p-Phenylazophenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (in toluene), not more than 3.0 percent.

Aniline, not more than 0.2 percent.

Amino-azo-benzene, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Red No. 18

Specifications

1-Xylylazoxylylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 2.0 percent.

Sulfated ash, not more than 2.0 percent.

Water soluble matter, not more than 0.5 percent.

Matter, insoluble in carbon tetrachloride, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 1.0 percent.

Amino-azo-xylene, not more than 0.2 percent.

Xylidine, not more than 0.2 percent.
beta-Naphthol, not more than 0.2 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

D&C Red No. 19

Specifications

3-Ethochloride of 9-o-carboxyphenyl-6-diethylamino-3-ethylimino-3-isoxanthene.

Volatile matter (at 135° C.), not more than 5.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts (from acid solution), not more than 0.5 percent.
Diethyl-m-aminophenol, not more than 0.2 percent.
Chlorides and sulfates of sodium, not more than 2.0 percent.
Mixed oxides, not more than 1.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 92.0 percent.

D&C Red No. 20

Specifications

3-Ethoacetate of 9-o-carboxyphenyl-6-diethylamino-3-ethylimino-3-isoxanthene.

Volatile matter (at 135° C.), not more than 5.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts (from acid solution), not more than 0.5 percent.
Diethyl-m-aminophenol, not more than 0.2 percent.
Sodium acetate, not more than 2.0 percent.
Mixed oxides, not more than 1.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 92.0 percent.

D&C Orange No. 5

Specifications

4,5-Dibromo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.
Insoluble matter (alkaline solution), not more than 1.0 percent.
Ether extracts (from alkaline solution), not more than 0.5 percent.
Sodium chloride, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free bromine, not more than 0.02 percent.
Permitted range of organically combined bromine in pure dye, 31.0–35.0 percent.
Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Orange No. 6

Specifications

Disodium salt of 4,5-dibromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts, not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 5.0 percent.
Mixed oxides, not more than 1.0 percent.
Free bromide, not more than 0.02 percent.
Permitted range of organically combined bromine in pure dye, 28.0–32.0 percent.
Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 7

Specifications

Dispotassium salt of 4,5-dibromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts, not more than 0.5 percent.
Chlorides and sulfates of potassium, not more than 5.0 percent.
Mixed oxides, not more than 1.0 percent.
Free bromide, not more than 0.02 percent.
Permitted range of organically combined bromide in pure dye, 26.0–30.0 percent.
Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 8

Specifications

4,5-Dichloro-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.
Insoluble matter (alkaline solution), not more than 1.0 percent.
Ether extracts (from alkaline solution), not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free chlorine, not more than 0.02 percent.
Permitted range of organically combined chlorine in pure dye, 16.0–19.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Orange No. 9

Specifications

Disodium salt of 9-o-carboxyphenyl-4,5-dichloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts, not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 5.0 percent.
Mixed oxides, not more than 1.0 percent.
Free chlorine, not more than 0.02 percent.
Permitted range of organically combined chlorine in pure dye, not more than 14.5–17.5 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Orange No. 10

Specifications

4,5-Diiodo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.
Insoluble matter (alkaline solution), not more than 1.0 percent.
Ether extracts (from alkaline solution), not more than 0.5 percent.
Sodium chloride, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free iodine, not more than 0.05 percent.
Permitted range of organically combined iodine in pure dye, 41.5–45.5 percent.
Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 11

Specifications

Disodium salt of 9-o-carboxyphenyl-6-hydroxy-4,5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts, not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free iodine, not more than 0.05 percent.
Permitted range of organically combined iodine in pure dye, 38.5–42.5 percent.
Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 12

Specifications

Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-4,5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 36.5–40.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 13

Specifications

Diammonium salt of 9-o-carboxyphenyl-6-hydroxy-4,5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of ammonium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 39.0–43.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 21

Specifications

2,4,5,7-Tetrabromo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 47.5–51.5 percent.

Pure dye (as determined gravimetrically), not less than 93.0 percent.

D&C Red No. 22

Specifications

Disodium salt of 2,4,5,7-tetrabromo-9-o-carboxyphenyl -6-hydroxy - 3 - isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 44.5–48.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 23

Specifications

Dipotassium salt of 2,4,5,7-tetrabromo-9 - o - carboxyphenyl - 6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 15.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye (free from water or alcohol of crystallization), 42.0–46.0 percent.

Pure dye (as determined gravimetrically), not less than 80.0 percent.

D&C Red No. 24

Specifications

2,4,5,7-Tetrachloro-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Red No. 25

Specifications

Disodium salt of 9-o-carboxyphenyl-2, 4,5,7 - tetrachloro - 6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 26.0–29.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 26

Specifications

Dipotassium salt of 9-o-carboxyphenyl - 2,4,5,7 - tetrachloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 24.5–27.5 percent.

Pure dye (as determined gravimetrically), not less 85.0 percent.

D&C Red No. 27

Specifications

2,4,5,7 - tetrabromo - 12,13,14,15-tetra - chloro-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 38.5–42.5 percent.

Permitted range of organically combined chlorine in pure dye, 16.0–19.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Red No. 28

Specifications

Disodium salt of 2,4,5.7-tetrabromo-9-(3,4,5,6-tetrachloro-o-carboxyphenyl) -6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye 36.5–40.5 percent.

Permitted range of organically combined chlorine in pure dye, 16.0–18.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 14

Specifications

4,5,15 - Tribromo - 2,7 - dicarboxy-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Insoluble matter (alkaline solution), not more than 0.3 percent.

Soluble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye 36.0–40.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

D&C Red No. 29

Specifications

1,4,5,8,15 - Pentabromo - 2,7 - dicarboxy-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Insoluble matter (alkaline solution), not more than 0.3 percent.

Soluble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 47.0–51.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

D&C Orange No. 15

Specifications

1,2-Anthraquinonediol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Water soluble matter, not more than 1.5 percent.

Ether insoluble matter, not more than 1.0 percent.

Sodium chloride, not more than 1.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

Melting point, not less than 285° C.

D&C Red No. 30

Specifications

5,5'-Dichloro-3,3'-dimethyl-thioindigo.

Volatile matter (at 135° C.), not more than 5.0 percent.

Matter, insoluble in xylene, not more than 1.0 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Orange No. 3

Specifications

Disodium salt of 1-phenylazo-2-naphthol-6,8-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Orange No. 4

Specifications

Monosodium salt of 1-p-sulfophenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Brown No. 1

Specifications

Monosodium salt of 4-p-sulfophenylazo-2-(2,4-xylylazo)-1,3-resorcinol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

m-Xylidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Blue No. 3

Specifications

1-Hydroxy-4-p-toluino-anthraquinone.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in carbon tetrachloride, not more than 1.5 percent.

p-Toluidine, not more than 0.2 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 96.0 percent.

Melting point, not less than 185° C.

D&C Blue No. 4

Specifications

Diammonium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl]-(2-sulfoniumphenyl)-methylene)-[1-(N-ethyl-N-p-sulfobenzyl) - Δ2,5-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of ammonium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Blue No. 5

Specifications

Monosodium salt of 1-methylamino-4-(o-sulfo-p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined nitrogen or sulphur), not less than 80.0 percent.

D&C Blue No. 6

Specifications

Indigotin.

Volatile matter (at 135° C.), not more than 5.0 percent.

Sulfated ash, not more than 2.0 percent.

Matter, insoluble in dichlorhydrin, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

D&C Black No. 1

Specifications

Disodium salt of 8-amino-7-p-nitrophenylazo-2-phenylazo-1-naphthol - 3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

p-Nitroaniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Lakes

Any lake, made as hereinafter prescribed, of

(1) a straight color listed above in this subsection or in section 135.03; or

(2) the aluminum salt prepared from

FD&C Green No. 1
FD&C Green No. 2
FD&C Green No. 3
FD&C Yellow No. 1
FD&C Yellow No. 5
FD&C Yellow No. 6
FD&C Red No. 1
FD&C Red No. 2
FD&C Red No. 3
FD&C Orange No. 1
D&C Red No. 5
D&C Red No. 6
D&C Red No. 10
D&C Red No. 19
D&C Red No. 20
D&C Red No. 21
D&C Orange No. 4
D&C Orange No. 8
D&C Orange No. 10
D&C Blue No. 4
D&C Blue No. 6; or

the barium salt prepared from

FD&C Green No. 1
FD&C Green No. 2
FD&C Green No. 3
FD&C Yellow No. 1
FD&C Yellow No. 5
FD&C Yellow No. 6
FD&C Red No. 1
FD&C Red No. 2
FD&C Orange No. 1
FD&C Blue No. 2
D&C Yellow No. 10
D&C Red No. 5
D&C Red No. 8
D&C Red No. 10
D&C Red No. 14
D&C Orange No. 4
D&C Blue No. 4; or

the zirconium salt prepared from

FD&C Yellow No. 5; or

the calcium salt prepared from

FD&C Red No. 2
D&C Red No. 5
D&C Red No. 6
D&C Red No. 14
D&C Orange No. 15;

or the calcium salt prepared from D&C Red No. 31 (which is the calcium salt of 3-hydroxy-4-phenylazo-2-naphthoic acid). Such lake shall be made by the extension of one such straight color or one such salt on one or any combination of two or more of the following substrata; alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, or aluminum benzoate.

Specifications

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake under the designation "Lakes" in subsection (a) shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

First, in case the lake is made from a straight color listed in subsection (a) before "Lakes" or in section 135.03, the name under which such color is so listed; or in case the lake is made from a salt included in clause (2) under "Lakes" in subsection (a), the name of the color, as used in such clause, from which such salt is prepared; but in either case, if such name contains the symbol "FD&C," such symbol shall be replaced by the symbol "D&C."

Second, the name of the metallic base chemically combined in the color; and,

Third, the word "lake."

(For example, the name of a lake prepared from the color D&C Red No. 9 extended upon a substratum would be "D&C Red No. 9—Barium Lake", and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum would be "D&C Green No. 1—Aluminum Lake.")

SEC. 135.05 *List of straight colors and specifications for their certification for use in externally applied drugs and cosmetics.*—(a) A batch of a straight color listed herein may be certified, in accordance with the provisions of these regulations, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specifications herein set forth for such color.

Ext D&C Yellow No. 1

Specifications

Monosodium salt of 4-m-sulfophenylazo-diphenylamine.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Chloroform soluble matter, not more than 0.5 percent.

Diphenylamine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 7.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Yellow No. 2

Specifications

Calcium salt of 4-m-sulfophenylazo-diphenylamine.

Volatile matter (at 135° C.), not more than 10.0 percent.

Chloroform soluble matter, not more than 0.5 percent.

Diphenylamine, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Yellow No. 3

Specifications

Monosodium salt of 5-hydroxy-3-methyl - 4 - phenylazo-1 -p-sulfophenyl-pyrazole.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Yellow No. 4

Specifications

Monosodium salt of 1-(4-chloro-o-sulfophenyl)-5-hydroxy-3-methyl-4-[p-(p-tolylsulfonoxy)-phenylazo]-pyrazole.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

p-Aminophenol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Red No. 1

Specifications

Disodium salt of 8 - acetamindo-2-p-acetamidophenylazo - 1-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

p-Amino acetanilid, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Red No. 2

Specifications

Trisodium salt of 1-o-carboxyphenylazo-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Red No. 3

Specifications

Disodium salt of 9-o-carboxyphenyl-6- (4- sulfo-o-toluino) -3- o-tolylimino-3-isoxanthene.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

o-Toluidine, not more than 0.2 percent.

Mixed oxides, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.

Ext D&C Red No. 4

Specifications

12, 15-Dichloro-2, 4, 5, 7-tetraiodo-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined iodine in pure dye, not more than 54.0–58.0 percent.

Permitted range of organically combined chlorine in pure dye, 7.0–8.5 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

Ext D&C Red No. 5

Specifications

Disodium salt of 9-(3,6-dichloro-o-carboxyphenyl) - 6 - hydroxy - 2,4,5,7 - tetraiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined iodine in pure dye, 51.5–55.5 percent.

Permitted range of organically combined chlorine in pure dye, 6.8–8.3 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

Ext D&C Red No. 6

Specifications

Dipotassium salt of 9-(3,6-dichloro-o-carboxyphenyl) - 6 hydroxy - 2,4,5,7 - tetraiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined iodine in pure dye, 50.0–54.0 percent.

Permitted range of organically combined chlorine in pure dye, 6.5–8.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

Ext D&C Red No. 7

Specifications

Monosodium salt of 3,4-dihydroxy-2-anthraquinonesulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Free acid as H_2SO_4, not more than 0.01 percent.

Pure dye (by spectrophotometric determination), not less than 82.0 percent.

Ext D&C Blue No. 1

Specifications

3-Methochloride of 9-dimethylamino-3-methylimino-3-isophenothiazine.

Volatile matter (at 110° C.), not more than 16.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Dimethyl aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Blue No. 2

Specifications

Zinc chloride double salt of 3-methochloride of 9-dimethylamino-3-methylimino-3-isophenothiazine.

Volatile matter (at 110° C.), not more than 15.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Dimethyl aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Zinc chloride (not a part of the dye), not more than 1.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Lakes

Any lake, made as hereinafter prescribed, of—

(1) a straight color listed above in this subsection; or

(2) the aluminum salt prepared from

EXT D&C Yellow No. 1
EXT D&C Yellow No. 3 or

the barium salt prepared from

EXT D&C Yellow No. 3
EXT D&C Red No. 2 or

the calcium salt prepared from

EXT D&C Red No. 2

Such lake shall be made by the extension of one such straight color or one such salt on one or any combination of two or more of the following substrata:

alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, or aluminum benzoate.

Specifications

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake under the designation "Lakes" in subsection (a) shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

First, in case the lake is made from a straight color listed in subsection (a) before "Lakes", the name under which such color is so listed; or in case the lake is made from a salt included under clause (2) under "Lakes" in subsection (a), the name of the color, as used in such clause, from which such salt is prepared.

Second, the name of the metallic base chemically combined in the color; and,

Third, the word "lake."

(For example, the name of a lake prepared from the color Ext D&C Yellow No. 2 extended upon a substratum would be "Ext D&C Yellow No. 2—Calcium Lake", and a lake prepared by extending the barium salt prepared from Ext D&C Red No. 2 upon the substratum would be "Ext D&C Red No. 2—Barium Lake".)

SEC. 135.06 *Mixtures which may be certified.* (a) A batch of a mixture which contains no straight color listed in section 135.04 or 135.05 may be certified, in accordance with the provisions of these regulations, for use in food, drugs, and cosmetics, if—

(1) each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) No diluent (except resins, natural gum, and pectin) in such mixture is a non-nutritive substance, unless such mixture is for use in coloring a food specified in the request for certification of such batch submitted in accordance with section 135.08 (c), and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in section 135.05, or which contains a diluent not permitted by clause (3) of paragraph (a) of this section, may be certified, in accordance with the provisions of these regulations, for use only in drugs and cosmetics, if—

(1) each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture, and

(2) each diluent in such batch of mixture is harmless and suitable for use therein.

(c) A batch of a mixture which contains a straight color listed in section 135.05 may be certified, in accordance with the provisions of these regulations, for use only in externally applied drugs and cosmetics, if—

(1) each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture; and

(2) each diluent in such batch of mixture is harmless and suitable for use therein.

SEC. 135.07 *Sampling, storage, and packaging*—(a) A sample of a coal-tar color which is to accompany a request for certification submitted in accordance with section 135.08 shall be taken from the batch covered by such request only after such batch has been so thoroughly mixed as to be of uniform composition throughout. Immediately after such sample is taken it shall be closed in a package of such kind as to prevent change in the composition of such sample. Such package shall be labeled to show conspicuously the name and post office address of the person submitting such request, the name of such color, and the batch number and quantity of such batch.

(b) Immediately after such sample is taken such batch shall be stored in containers of such kind as to prevent change in the composition of such color, or closed in packages for shipment or delivery, and so held until such batch is certified or certification thereof is refused. If such batch is certified and at the time of certification such batch or any part thereof is so stored, such storage shall be maintained until such batch or part is—

(1) closed in such packages,

(2) used by the person who obtained such certification as an ingredient in a batch of a mixture on which such person submits a request for certification in accordance with section 135.08, or

(3) used by such person in coloring a food, drug, or cosmetic, in accordance with the use for which such batch was certified.

(c) The package in which a coal-tar color is closed for shipment or delivery shall be of such kind as to prevent change in the composition of such color, and shall be so closed or sealed that such package cannot be opened without destroying such package or seal.

(d) For the purposes of these regulations an unavoidable change in the moisture content of a coal-tar color caused by ordinary and customary exposure that occurs in good storage, packing, and distribution practice, shall not be considered to be a change in the composition of such color.

SEC. 135.08 *Requests for certification.*—(a) A request for certification of a batch of a coal-tar color shall be addressed to the Food and Drug Administration, U. S. Department of Agriculture, Washington, D. C. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) Except in the case of a request submitted under paragraph (d) of this section, a person who requests the certification of a batch of a straight color shall submit as part of his request statements showing—

(1) whether or not he manufactured such batch, and if he did not, the name and post office address of the manufacturer thereof; and

(2) the name of such color, as listed in section 135.03, 135.04, or 135.05, and the batch number and quantity of such batch.

(3) In the case of a lake, the process whereby such lake is made, including the name or names of the substrata present and the quantity thereof used for such batch. Such request shall be accompanied by a one-half pound sample taken from such batch and accurately representative thereof, and by payment of the fee prescribed by section 135.15 (a) (1). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such batch complies with the requirements laid down by section 135.09 (a) for the issuance of a certificate.

(c) Except in the case of a request submitted under paragraph (d) of this section, a person who requests certification of a batch of a mixture shall submit as part of his request statements—

(1) to the effect that he mixed such batch;

(2) showing the name of such mixture, and the batch number and quantity of such batch;

(3) showing the lot number of each coal-tar color used as an ingredient in mixing such batch, the quantity of such color so used, and that such color has not changed in composition in any manner whatever since certification, except by mixing into such batch;

(4) showing the name, quality, and quantity of each diluent used as an ingredient in mixing such batch;

(5) in case such mixture contains a diluent permitted by clause (3) of section 135.06 (a) only because such diluent does not become a component of a food colored by such mixture, specifying the name of such food; and

(6) describing fully the process of mixing, with special reference to the precautions taken to render such batch uniform in composition.

Such request shall be accompanied by a one-fourth pound sample taken from such mixed batch and accurately representative thereof, and by payment of the fee prescribed by section 135.15 (a) (2). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such mixed batch complies with the requirements laid down by section 135.09 (a) for the issuance of a certificate.

(d) A person who requests the certification of a batch made by repacking a coal-tar color from a batch previously certified under these regulations, shall submit as part of his request statements—

(1) to the effect that he made the batch on which he requests certification by repacking such color, and that such color has not changed in composition in any manner whatever since such previous certification; and

(2) showing the lot number of such previously certified batch, the name of such repacked color, and the batch number and quantity of such repacked batch. Such request shall be accompanied by a one-fourth pound sample taken from such repacked batch and accurately representative thereof, and by payment of the fee prescribed by section 135.15 (a) (2). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such repacked batch complies with the requirements of section 135.09 (a) for the issuance of a certificate.

SEC. 135.09 *Certification.* (a) If the Food and Drug Administration determines, after such investigation as it considers to be necessary, that—

(1) a request submitted in accordance with section 135.08 appears to contain no untrue statement of a material fact;

(2) in the case of a straight color, such color conforms to the specifications set forth therefor in sections 135.02, 135.03, 135.04, and 135.05;

(3) in the case of a mixture containing a diluent, such diluent is harmless and suitable for use therein; and

(4) the batch covered by such request otherwise appears to comply with these regulations, the Food and Drug Administration shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by section 135.10, is a certified batch for use in food, drugs, and cosmetics, or for use only in drugs and cosmetics, or for use only in externally applied drugs and cosmetics, as the case may be.

(b) If the Food and Drug Administration determines, after such investigation as it considers to be necessary, that a request submitted in accordance with section 135.08, or the batch of coal-tar color covered by such request, does not comply with the requirements laid down by paragraph (a) of this section for the issuance of a certificate, the Food and Drug Administration shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating its reasons for refusal.

SEC. 135.10 *Limitations of certificates.* (a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and coal-tar color from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with these regulations.

(b) If, between the time a sample of coal-tar color accompanying a request for certification is taken and the time a certificate covering the batch of such color is received by the person to whom it is issued, any such color becomes changed in composition in any manner whatever, such certificate shall not be effective with respect to such changed color, and such changed color shall be considered to be from a batch that has not been certified in accordance with these regulations.

(c) If, at any time after a certificate is received by the person to whom it is issued, any color from the batch covered by such certificate becomes changed in composition in any manner whatever, such certificate shall expire with respect to such changed color. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with these regulations; except that such color shall not be so considered for the purpose of certifying a batch of a mixture in which such color was used as an ingredient, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any coal-tar color covered thereby if the package in which such color was closed for shipment or delivery is opened, unless opened solely for repacking by the person to whom such certificate was issued. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with these regulations; except that such color shall not be so considered—

(1) when such color is used, subject to the restrictions prescribed by paragraphs (f), (g) and (h) of this section, in coloring a food, drug, or cosmetic;

(2) for the purpose of certifying a batch made by repacking such color; or

(3) for the purpose of certifying a batch of a mixture in which such color is used as an ingredient.

(e) A certificate shall not be effective with respect to a package of coal-tar color, and such color shall be considered to be from a batch that has not been certified in accordance with these regulations, if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by section 135.11 to appear thereon.

(f) If a mixture from a batch containing a diluent permitted by clause (3) of section 135.06 (a) only because such diluent does not become a component of a food colored by such mixture is used in coloring another food, such mixture so used shall be considered to be from a batch that has not been certified in accordance with these regulations.

(g) If coal-tar color from a batch which was certified for use in drugs and cosmetics only is used in coloring a food; such color so used shall be considered to be from a batch that has not been certified in accordance with these regulations.

(h) If a coal-tar color from a batch which was certified for use only in externally applied drugs and cosmetics is used in food or in other drugs or other cosmetics, such color so used shall be considered to be from a batch that has not been certified in accordance with these regulations.

SEC. 135.11 *Labeling.* (a) The label on each package of coal-tar color from a batch that has been certified in accordance with these regulations shall bear, in addition to other words, statements, and information required by or under authority of the Act to appear on such label—

(1) the name of such color;

(2) the lot number of such batch;

(3) the percentage of pure dye in such color; and,

(4) in case such batch was certified for use only in drugs and cosmetics, the statement *"Not for use in coloring food"*; or in case such batch was certified for use only in externally applied drugs and cosmetics, the statement *"Not for use in coloring food, or in coloring any drug or cosmetic used internally or on the lips or any mucuous membrane"*; or in case such batch is a mixture containing a diluent permitted by clause (3) of section 135.06 (a) only because such diluent does not become a component of a food colored by such mixture, the statement *"Not for use in coloring any food except _____"* (the blank to be filled in by the name of such food).

(b) The statement of the percentage of pure dye in a coal-tar color shall express the minimum percentage by weight and shall be the statement of the percentage of the pure dye stated

in the certificate effective with respect to such batch of a coal-tar color.

(c) The name by which a straight color is designated on its label shall be the name by which such color is listed in section 135.03, 135.04, or 135.05.

(d) No batch of a mixture shall be certified under these regulations if—

(1) the name of such mixture is false or misleading in any particular; or

(2) the name of such mixture is the same as or simulates the name of a previously certified batch of a mixture containing a different substance, or a different percentage of a pure dye; but this provision shall not apply if the person who requests certification of such batch is the owner of such name and has given three months' written notice to the Food and Drug Administration specifying the change to be made in the composition of such mixture.

SEC. 135.12 *Records of distribution.* (a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the coal-tar color from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, such person, at all reasonable hours until at least one year after disposal of all such color, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show—

(1) each quantity used by such person from such batch and the date and kind of such use;

(2) the date and quantity of each shipment or delivery from such batch, and the name and post office address of the person to whom such shipment or delivery was made.

SEC. 135.13 *Authority to refuse certification service.* When it appears to the Secretary that a person has—

(1) obtained a certificate through fraud or misrepresentation of a material fact;

(2) falsified the records required to be kept by section 135.12; or

(3) failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by such section,

the Secretary may immediately suspend service to such person under these regulations, and may continue such suspension unless and until such person shows adequate cause why such suspension should be terminated.

SEC. 135.14 *Procedure for admitting colors to listing.* (a) An application for the admission of a coal-tar color to listing in section 135.03, 135.04, or 135.05 shall be accompanied by—

(1) full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

(2) a full statement of the percentages and compositions of the pure dye and all intermediates and other impurities contained in such color;

(3) a full statement showing the identity, purity, and quantity or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) a full description of practical and accurate methods of analysis for the quantitative determination of the pure dye and of all intermediates and other impurities contained in such color;

(5) a full description of practical and accurate methods for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith;

(6) a five-pound sample of such color (unless the Food and Drug Administration authorizes or requires submission of other quantity suitable to the need for investigation) taken from a batch produced under practical manufacturing conditions, and accurately representative of such batch; and

(7) the advance deposit prescribed by section 135.15 (b) (2).

(b) If the Secretary determines, after such investigation as he considers to be necessary, that—

(1) such color is harmless and suitable for use in foods, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics;

(2) practical and accurate methods of analysis exist for the quantitative determination of the pure dye and all intermediates and other impurities contained in such color; and

(3) practical and accurate methods exist for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith,

the Secretary, for the purpose of listing such color in section 135.03, 135.04, or 135.05, shall proceed with a proposed amendment to these regulations as prescribed by section 701 (e) of the Act.

(c) If the Secretary, after such investigation as he considers to be necessary, determines that such color does not comply with the requirements laid down by paragraph (b) of this section with respect to procedure for the purpose of listing such color in section 135.03, 135.04, or 135.05, the Secretary shall give notice thereof to the applicant, stating the respects in which such color does not so comply.

SEC. 135.15 *Fees.* (a) (1) The fee for the service provided by these regulations, in the case of each request for certification submitted in accordance with section 135.08 (b), shall be $15.

(2) The fee for the service provided by these regulations, in the case of each request for certification submitted in accordance with section 135.08 (c) or (d) shall be $8.

(b) (1) The fee for the service provided by these regulations, in the case of each application for the admission of a coal-tar color to listing in section 135.03, 135.04, or 135.05, shall be the cost incurred by the Department in making the investigations contemplated by section 135.14 (b) and (c).

(2) Such application shall be accompanied by an advance deposit of $500 to cover such fee, and thereafter advance deposits of the same amount (unless the Food and Drug Administration authorizes deposit in other amount) shall be made whenever necessary to prevent arrears in the payment of such fee. Any excess advance deposit so made shall be returned to the applicant after the close of such investigation;

(c) All fees required by these regulations should be paid by money-order, bank draft or certified check, drawn to the order of the Treasurer of the United States, collectible at par, at Washington, D. C.

(d) All earned fees shall be deposited in the Treasury of the United States to the credit of Miscellaneous Receipts, Department of Agriculture.

Time Allowed to File Objections and Exceptions

Each and every interested person who desires to file objections to any matter set out in the foregoing suggested findings of fact, conclusions in the form of Regulations, or Order, or a written statement, or brief, in support of any exception to any ruling of the Presiding Officer at said hearing, shall, within ten days after the receipt of the copy of the FEDERAL REGISTER containing this report, transmit to and file with the Hearing Clerk, Office of the Solicitor, United States Department of Agriculture, Washington, District of Columbia, such objections, or exceptions, in writing, accompanied by a brief statement concerning each such objection or exception, referring specifically to the relevant suggested findings, conclusions in the form of Regulations, or Order to which objections are filed, to such exceptions, and to the pertinent pages of the transcript of the evidence and the proceedings.

This 31st day of March 1939.

Respectfully submitted.

[SEAL] FRANK S. HASSELL,
Presiding Officer.

[F. R. Doc. 39-1155; Filed, April 5, 1939; 12:09 p. m.]

SECURITIES AND EXCHANGE COMMISSION.

United States of America—Before the Securities and Exchange Commission

At a regular session of the Securities and Exchange Commission held at its office in the City of Washington, D. C., on the 6th day of April, A. D. 1939.

[File No. 54–12]

IN THE MATTER OF COLUMBIA GAS & ELECTRIC CORPORATION

ORDER ALLOWING PETITION TO INTERVENE

Upon written request, by John D. Ellis, Esq., on behalf of the City of Cincinnati, to intervene in the above named proceedings;

It is hereby ordered, That said request is granted.

By the Commission.

[SEAL] FRANCIS P. BRASSOR, *Secretary.*

[F. R. Doc. 39–1180; Filed, April 7, 1939; 11:45 a. m.]

United States of America—Before the Securities and Exchange Commission

At a regular session of the Securities and Exchange Commission held at its office in the City of Washington, D. C., on the 3rd day of April, A. D. 1939.

IN THE MATTER OF UNION ELECTRIC COMPANY OF MISSOURI

ORDER FOR PUBLIC INVESTIGATION DESIGNATING OFFICER FOR TAKING TESTIMONY

It appearing to the Commission that Union Electric Company of Missouri is a subsidiary of North American Edison Company and The North American Company, both registered holding companies within the meaning of the Public Utility Holding Company Act of 1935; and

It further appearing to the Commission that Union Electric Company of Missouri, North American Edison Company and The North American Company, each has securities registered on one or more national securities exchanges under the Securities Exchange Act of 1934; and

It further appearing to the Commission that Union Electric Company of Missouri and The North American Company each has securities registered under the Securities Act of 1933; and

It further appearing to the Commission that Union Electric Company of Missouri is itself a holding company and as such has applied to the Commission for exemption under Section 3 (a) (2) of the Public Utility Holding Company Act of 1935, which application is now pending before the Commission; and

It further appearing to the Commission that Union Electric Company of Missouri, pursuant to the aforesaid registrations and in support of the aforesaid application for exemption, has filed financial statements, balance sheets, profit and loss statements, income accounts and other reports of operations with the Commission for the calendar years 1934, 1935, 1936 and 1937 and for the first nine months of 1938; and

It further appearing to the Commission that North American Edison Company and The North American Company, pursuant to the aforesaid registrations have filed with the Commission financial statements, balance sheets, profit and loss statements, income accounts and other reports of operation for the calendar years 1933, 1934, 1935, 1936 and 1937, and for the first six months of 1938, which reports are based, in part, upon financial statements, balance sheets, profit and loss statements, income accounts and other reports of operations furnished to said companies by Union Electric Company of Missouri, which information became and becomes a basis for, and was and is incorporated in, applications, reports, documents, accounts and records filed and kept under the provisions of the Public Utility Holding Company Act of 1935; and

The Commission having reasonable grounds to believe that from January 1, 1933, to date, Union Electric Company of Missouri collected, and is now collecting, sums of money from employees, officers, directors, attorneys, contractors and other persons through the medium of padded expense accounts, return of fees and otherwise, which collections are not properly contained in or reflected on the books, records or accounts of Union Electric Company of Missouri; and

The Commission having further reasonable grounds to believe that from January 1, 1933, to date, the books, records and accounts of Union Electric Company of Missouri contain entries purporting to show charges for legal fees, expenses incidental to necessary legal work, travel, entertainment and miscellaneous expenses of officers, directors, employees and agents, which were not incurred as set forth in said books, records and accounts; and

The Commission having further reasonable grounds to believe that from January 1, 1933, to date, Union Electric Company of Missouri made contributions in connection with the candidacy, nomination, election and appointment of persons (whose names are unknown to the Commission) for and to offices and positions in the Government of States, political sub-divisions of States, and agencies, authorities and instrumentalities of the foregoing; and made contributions to and in support of political parties; committees and agencies thereof; and

The Commission having further reasonable grounds to believe that the amounts of the contributions mentioned in the preceding paragraph and the name or names of the person or persons, organizations or agencies to whom said contributions were paid, are not entered in or shown by the books, records and accounts of Union Electric Company of Missouri; and

The Commission having further reasonable grounds to believe that since January 1, 1933, Union Electric Company of Missouri has received various sums of money (the dates and amounts of which are not known to the Commission), which receipts are not properly entered on the books, records and accounts of Union Electric Company of Missouri, and has expended various sums of money (the dates and amounts of which are not known to the Commission), which expenditures are not entered in or otherwise properly reflected on the books, records and accounts of Union Electric Company of Missouri; and

The Commission having further reasonable grounds to believe that the financial statements, balance sheets, profit and loss statements, income accounts and other reports of operations filed with the Commission by Union Electric Company of Missouri pursuant to the aforesaid registrations and the aforesaid application for exemption were false and misleading with respect to various items of receipts and expenditures whereby the expenses were made to appear substantially greater than was actually the fact and the receipts were made to appear substantially less than was actually the fact; and

The Commission having further reasonable grounds to believe that Union Electric Company of Missouri has violated the provisions of Section 24 of the Securities Act of 1933, of Section 32 (a) of the Securities Exchange Act of 1934 and of Sections 12 (h) and 29 of the Public Utility Holding Company Act of 1935; and

It further appearing to the Commission necessary and proper and in the public interest to determine the amount and other details of any receipts or expenditures of Union Electric Company since January 1, 1933, and the extent to which such receipts and expenditures are entered on or omitted from the books, records and accounts of Union Electric Company of Missouri and have been and are now reported to North American Edison Company and The North American Company and the extent to which the acts and practices hereinbefore mentioned may have falsified, distorted or otherwise made incorrect, financial statements, balance sheets, profit and loss statements, income accounts or other reports of operations filed with the Commission by Union Electric Company of Missouri, North American Edison Company or The North American Company, for the periods hereinbefore mentioned.

It is ordered, Pursuant to Sections 19 (a) and 20 (a) of the Securities Act of 1933, Section 21 (a) of the Securities Exchange Act of 1934 and Sections 18 (a) and 18 (b) of the Public Utility Holding Company Act of 1935, that a public investigation be held to determine the facts, conditions, practices and matters above referred to, to aid (1) in the enforcement of each of said Acts; (2) in prescribing rules and regulations pursuant to provisions of Sections 7, 10 (b) and 19 (a) of the Securities Act of 1933, Sections 12 and

13 of the Securities Exchange Act of 1934 and Sections 3 (d), 6 (d), 7, 12, 13, 15, 17 (c), 20 (a) and 23 (a) of the Public Utility Holding Company Act of 1935 and other pertinent provisions of each of said Acts; and (3) in securing information to serve as a basis for recommending further legislation concerning any matters to which any of such Acts relates, as may appear to the Commission to be necessary and appropriate; and to determine whether or not Union Electric Company of Missouri has violated the provisions of Section 24 of the Securities Act of 1933, of Section 32 (a) of the Securities Exchange Act of 1934 and of Sections 12 (h) and 29 of the Public Utility Holding Company Act of 1935; and

It is further ordered, Pursuant to Section 19 (b) of the Securities Act of 1933, Section 21 (b) of the Securities Exchange Act of 1934 and Section 18 (c) of the Public Utility Holding Company Act of 1935, for the purposes of such public investigation, that James G. Ewell, an officer of the Commission, is hereby designated to administer oaths and affirmations, subpena witnesses, compel their attendance, take evidence, require the production of any books, papers, correspondence, memoranda or other records deemed relevant or material to the inquiry, and to perform all other duties in connection therewith authorized by law; and

It is further ordered, That a public investigation for the taking of testimony and the production of evidence begin on the 24th day of April, 1939, at 10:30 A. M., or as soon thereafter as counsel can be heard, at the office of the Securities and Exchange Commission, 1778 Pennsylvania Avenue, Washington, D. C., and continue thereafter at such times and places as said officer may determine.

By the Commission.

[SEAL] FRANCIS P. BRASSOR,
Secretary.

[F. R. Doc. 39-1181; Filed, April 7, 1939; 11:45 a. m.]

United States of America—Before the Securities and Exchange Commission

At a regular session of the Securities and Exchange Commission held at its office in the City of Washington, D. C., on the 7th day of April, A. D. 1939.

[File No. 32-139]

IN THE MATTER OF HOOSIER GAS CORPORATION

NOTICE OF AND ORDER FOR HEARING

Applications, pursuant to sections 6 (b) and 10 (a) (3) of the Public Utility Holding Company Act of 1935, having been duly filed with this Commission by the above-named party;

It is ordered That a hearing on such matters be held on April 26, 1939, at 10:00 o'clock in the forenoon of that day, at the Securities and Exchange Building, 1778 Pennsylvania Avenue, NW., Washington, D. C. On such day the hearing-room clerk in room 1102 will advise as to the room where such hearing will be held. At such hearing, if in respect of any declaration, cause shall be shown why such declaration shall become effective.

It is further ordered, That Charles S. Moore or any other officer or officers of the Commission designated by it for that purpose shall preside at the hearings in such matter. The officer so designated to preside at any such hearing is hereby authorized to exercise all powers granted to the Commission under section 18 (c) of said Act and to a trial examiner under the Commission's Rules of Practice to continue or postpone said hearing from time to time.

Notice of such hearing is hereby given to such declarant or applicant and to any other person whose participation in such proceeding may be in the public interest or for the protection of investors or consumers. It is requested that any person desiring to be heard or to be admitted as a party to such proceeding shall file a notice to that effect with the Commission on or before April 21, 1939.

The matter concerned herewith is in regard to an application filed by Hoosier Gas Corporation (hereinafter called "Hoosier"), a subsidiary of Consolidated Electric and Gas Company, a registered holding company, pursuant to the provisions of the third sentence of Section 6 (b) of the aforesaid Act, for exemption from the provisions of Section 6 (a) of the assumption by applicant of the payment of the principal of and interest on a First Mortgage 4% Bond of Newton Pipe Line Company (hereinafter called "Newton") to be issued pursuant to its indenture of mortgage, dated January 1, 1939, in the aggregate principal amount of $55,000, due in annual installments of $5,500 each. The bond is to be issued to R. D. Brown, who owns 79% of capital stock of Newton, in payment of a like principal amount due to R. D. Brown. Newton will convey to applicant certain properties and assets in consideration for the assumption of the liability on the bond and the payment of cash.

In addition, Hoosier has filed an application pursuant to the provisions of Section 10 (a) (3) of the Act for approval of the acquisition of (1) a pipe line system of the Indiana Southwestern Gas Corporation (hereinafter called "Indiana") in consideration for the cancellation and surrender by applicant to Indiana of the old First Mortgage Bonds in the aggregate principal amount of $168,000 which were issued to applicant as security for advances made by it to Indiana for the purpose of building said pipe line and (2) the so-called Newton properties referred to hereinabove.

By the Commission.

[SEAL] FRANCIS P. BRASSOR,
Secretary.

[F. R. Doc. 39-1182; Filed, April 7, 1939; 11:46 a. m.]

United States of America—Before the Securities and Exchange Commission

At a regular session of the Securities and Exchange Commission held at its office in the City of Washington, D. C., on the 6th day of April, A. D. 1939.

[File No. 43-194]

IN THE MATTER OF SOUTHERN UTAH POWER COMPANY

NOTICE OF AND ORDER FOR HEARING

A declaration * * * pursuant to section 7 * * * of the Public Utility Holding Company Act of 1935, having been duly filed with this Commission by the above-named party;

It is ordered, That a hearing on such matter be held on April 25, 1939, at ten o'clock in the forenoon of that day, at the Securities and Exchange Building, 1778 Pennsylvania Avenue, NW., Washington, D. C. On such day the hearing-room clerk in room 1102 will advise as to the room where such hearing will be held. At such hearing, if in respect of any declaration, cause shall be shown why such declaration shall become effective.

It is further ordered, That, Willis E. Monty, or any other officer or officers of the Commission designated by it for that purpose shall preside at the hearings in such matter. The officer so designated to preside at any such hearing is hereby authorized to exercise all powers granted to the Commission under section 18 (c) of said Act and to a trial examiner under the Commission's Rules of Practice to continue or postpone said hearing from time to time.

Notice of such hearing is hereby given to such declarant or applicant and to any other person whose participation in such proceeding may be in the public interest or for the protection of investors or consumers. It is requested that any person desiring to be heard or to be admitted as a party to such proceeding shall file a notice to that effect with the Commission on or before April 20, 1939.

The matter concerned herewith is in regard to the proposed issue and sale to underwriters by Declarant of $99,000.00 aggregate principal amount of its First Mortgage 5½% Sinking Fund Bonds, Series A. Declarant states that the Bonds will, upon issuance thereof, be secured by a first lien on its physical property, and that the major portion of the proceeds from the sale of the Bonds will be expended for new construction.

Washington Gas and Electric Company is the parent of Declarant, and North American Gas and Electric Company, a registered holding company, is the parent of said Washington Gas and Electric Company.

By the Commission.

[SEAL] FRANCIS P. BRASSOR,
Secretary.

[F. R. Doc. 39-1170; Filed, April 7, 1939; 11:45 a. m.]